Supreme Court, U.S.
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No.

IN THE
Supreme Court of the United States

ASTELLAS PHARMA, INC.

Petitioner,

v.

LUPIN LIMITED and
LUPIN PHARMACEUTICALS, INC.

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit erred in ignoring the Court's binding precedent and finding product-by-process claims are not infringed by an identical product made by a different process?

PARTIES TO THE PROCEEDINGS AND CORPORATE DISCLOSURE STATEMENT

The parties to this proceeding are: Petitioner/Appellant Astellas Pharma, Inc. and Respondents/ Appellees Lupin Ltd. and Lupin Pharmaceuticals, Inc. Although Abbott Laboratories was an appellant below, it has not joined in this petition for *certiorari*.

The Federal Circuit's decision in 2007-1446 (this case) was a final decision disposing of all issues between the parties. On appeal, the Federal Circuit heard this case with 2007-1400, which involved the same patent and the same plaintiffs. That case was an appeal of a denial of a preliminary injunction to plaintiffs Astellas Pharma, Inc. and Abbott Laboratories and against defendants Sandoz, Inc., Sandoz GMBH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical. After remand, that case is currently stayed pending the outcome of this petition for *certiorari*. Astellas has provided a courtesy copy of this petition to the defendants in that case.

As required by the Court's Rule 29.6, Astellas Pharma, Inc. states that there is no parent corporation and no publicly held company owns 10% or more of its stock.

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Other Authorities

Donald S. Chisum, *5A Chisum on Patents* §18.01 (2007) 12

Donald S. Chisum, *Chisum on Patents* §8.05, 8-67 (1988) 21

Alan I. Cohen, Note, *A Prescription for the Treatment of Product-By-Process Patent Infringement*, 67 St. John's L. Rev. 923 (Fall, 1993)..... 26, 30

Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, Mich. St. L. Rev. 631 (Fall, 2007) 31

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Kevin J. McGough and Daniel P. Burke, *A Case for Expansive Patent Protection of Biotechnology Inventions*, 6 Harv. J. Law & Tec. 85 (Fall, 1992) 30

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Steven Seidenberg, *Process Perils: Ruling Narrows the Protection for Product-by-Process Patents*,
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Brian S. Tomko, Comment, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-By-Process Patents*, 60 Brooklyn L. Rev., 1693 (Winter, 1995).....26, 30, 32, 33

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PETITION FOR *CERTIORARI*

Petitioner Astellas Pharma, Inc. ("Astellas") respectfully seeks a writ of *certiorari* to the United States Court of Appeals for the Federal Circuit.

OPINION BELOW

The judgment of the Federal Circuit (en banc as to Section III(A)(2)) was entered on May 18, 2009. Due to an extension granted by the Chief Justice, this petition is due by September 16, 2009. The opinion of the court of appeals was reported at *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009). App. 1-88. The opinion of the district court granting summary judgment was entered on June 14, 2007 and was reported at *Lupin Ltd. v. Abbott Labs.*, 491 F. Supp. 2d 563 (E.D. Va. 2007). App. 89-103.

JURISDICTION

The judgment of the court of appeals, en banc as to Section III(A)(2), was entered on May 18, 2009. App. 1. On July 24, 2009, in Application 09A97, the Chief Justice extended the time to file the petition for *certiorari* until September 16, 2009. The jurisdiction of the Court is invoked under 28 U.S.C. § 1254(1). The jurisdiction of the Federal Circuit was invoked under 28 U.S.C. § 1295(a)(1).

CONSTITUTIONAL PROVISION INVOLVED

The United States Constitution, Art. I, Sec. 8, states that "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by

securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

STATEMENT OF THE CASE

I. Introduction

This case is without precedent. Here, the Federal Circuit *sua sponte* and over dissenting opinions went en banc and decided an important patent law issue with no notice to the public. In deciding that product-by-process "claims are treated as process claims for infringement," App. 81 (Newman, J., dissenting), the Federal Circuit devalued thousands of active patent claims and overturned 110 years of direct precedent that held that product-by-process claims do cover the product, regardless of how made. Worse still, the Federal Circuit violated the Court's precedent, which requires claims to be interpreted the same way for both infringement and invalidity. As the Court held 120 years ago, "[t]hat which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (U.S. 1889) (internal quotations omitted). The holding put forward by the en banc court here violates that rule, in that now a product described in a product-by-process claim will anticipate if earlier (even if the process used to create it is different from the process in the claim), but will *not* infringe if later (if the process used to create it is different from the process in the claim). Accordingly, the Court should grant the petition for *certiorari* and decide if it was proper for the Federal

Circuit to decide that this Court's binding precedent does not apply to an entire class of claims.

"In a product-by-process claim, a product is protected, even though the product is described by the process that produces it." Mark D. Passler, Comment, *Product-By-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act*, 49 U. Miami L. Rev. 233, 234 (Fall, 1994). By no later than 1891, the United States Patent Office had officially recognized that a product may be claimed by the process that makes that product (a "product-by-process" claim). *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891). Nevertheless, the Federal Circuit ignored that precedent, along with the Court's precedent, and decided to take away an inventor's right to claim a product by the process that makes that product (unless the product is made by the exact process described). In addition, its decision to go en banc with no notice to the public that it was overturning its own precedent on this issue violated its own procedural rules by not giving interested third parties a chance to comment. Thus, third parties lost the opportunity to demonstrate that product-by-process claims are even more important in the 21st century than they were in the 19th century, when they were first allowed.

II. Proceedings Below

Astellas is the assignee of U.S. Patent No. 4,935,507 ("the '507 patent"). The claims of the '507 patent are directed to certain crystalline forms of a compound known generically as cefdinir.

On June 14, 2007, the United States District Court for the Eastern District of Virginia granted summary judgment of non-infringement to Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"). The bases for that court's jurisdiction were 28 U.S.C. §§ 1331 and 1338.

The lower court found that Lupin did not infringe claims 2-5 (the only claims at issue) because Astellas did not present evidence that Lupin's product was made by practicing the processes set forth in claims 2-5. App. 96, 101-102. The lower court based its holding on *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), which held that a product-by-process claim is only infringed by a product that is made by the process described in the claim. *Id.* at 846-47. In so ruling, the *Atlantic* panel attempted to overrule *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), which had held just one year previously that a product-by-process claim is infringed by a product that is the same as the product described in the product-by-process claim, regardless of the process used to make the product. *Id.* at 1583.

Astellas appealed the lower court's decision to the Federal Circuit, which *sua sponte* went en banc to decide the product-by-process issue and then affirmed the lower court's decision. The one thing that may be said about the Federal Circuit's en banc decision is that it finally resolved the intra-circuit split between *Scripps* and *Atlantic*. With conflicting precedent, some district courts correctly followed

Scripps, *see, e.g., Trs. of Columbia University v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16, 31-32 (D. Mass. 2000); *SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 2002 U.S. Dist. LEXIS 25275, *16 (E.D. Pa., Dec. 20, 2002); *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 372 F. Supp. 2d 430, 436 (D. N.J. 2005); *Mannington Mills, Inc. v. Armstrong World Indus., Inc*, 218 F. Supp. 2d 594, 600 (D. Del. 2002); and some district courts (such as the one in this case) incorrectly followed *Atlantic*. *See, e.g., Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7, 10 (D. Mass. 1993). The reason it was correct for the district courts to follow *Scripps* and incorrect for the district courts to follow *Atlantic* is not because *Scripps* was correctly decided and *Atlantic* was incorrectly decided (although they were), but rather because the Federal Circuit follows the well-established rule that "[w]here there is a direct conflict [between decisions of the Federal Circuit], the precedential decision is the first." *Yunus v. Dept. of Veterans Affairs*, 242 F.3d 1367, 1372 n.2 (Fed. Cir. 2001) (internal quotation omitted). Thus, unless and until overturned by the en banc Federal Circuit, *Scripps* remained "good law." *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988) ("prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned en banc").

Now, of course, due to the Federal Circuit's *sua sponte* decision to go en banc and overturn *Scripps*, that case is no longer "good law." But, as the dissent noted, before overturning 110 years of precedent, at the very least, the Federal Circuit should have followed its own procedures and

publicized the fact that it was considering whether to change the law on product-by-process claims. But it failed to do so. Accordingly, numerous patent holders, including pharmaceutical and biological companies, were precluded from explaining why it is critical to their industries that product-by-process claims cover the product described and not the process used to make that product.

The law is now very clear that a product-by-process claim no longer covers the product, unless that product was made by the process described in the claim. Because the Federal Circuit has spoken clearly on this issue, it would not be proper for a party to even raise in a district court that a product-by-process claim covers a product made by a different process. *See* Fed. R. Civ. P. 11(b)(2). At most, a party could raise this argument before the district court and explain that, while the district court must follow precedent, the party is reserving the issue so that it can ask the Federal Circuit to go en banc again to reconsider the issue it just decided here, or seek a writ of *certiorari* to the Court regarding this issue. *Cf. Gomez-Astorga v. United States*, 2008 U.S. Dist. LEXIS 15808, *7 (D. Utah Feb. 29, 2008) (where issue was "foreclosed by clear precedent," the appeal was brought "only to preserve the issue on *certiorari* to the United States Supreme Court"). But considering that the Federal Circuit just decided this issue en banc, after letting the clear intra-circuit split fester on this issue for over 17 years, there is virtually no chance that the Federal Circuit would rehear this issue any time in the foreseeable future.

Finally, because the Federal Circuit has turned product-by-process claims into virtually pure process claims (albeit with an additional hurdle to cross because for patentability the patentee must prove the product is new, while for infringement purposes the relevant consideration is the process), there will be little point in patentees seeking product-by-process claims. Therefore, there will likely be few product-by-process claims for any court to review after the current product-by-process claims all expire within the next twenty years. Thus, for all practical purposes, this case will be the last chance for this Court to decide (and the public to comment on) whether the Federal Circuit properly overturned 110 years of precedent to turn product-by-process claims into little more than process claims.[1]

REASONS FOR GRANTING THE PETITION

Judge Newman, the author of *Scripps*, had some very specific criticisms of the majority opinion, which was written by Judge Rader, the author of *Atlantic*. These criticisms were in five main categories. As each of Judge Newman's criticisms

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[1] In addition, there would be no advantage for the Court to wait to decide this issue in some future case because 1) as the en banc court has clearly spoken on this issue, there should be little or no change to the law of product-by-process claims going forward, and 2) as the district court and a Federal Circuit panel will have no choice but to hold that product-by-process claims do not cover the product, there will probably be much less briefing and discussion on this issue in any future case (assuming *arguendo*, that there is even a future case that addresses this issue).

are correct, the Court should grant this petition and review the Federal Circuit's en banc opinion.[2]

I. By Failing to Follow Its Own Procedures, the En Banc Majority Took Away an Entire Class of Patents without Receiving Any Input from the Public

Judge Newman's first criticism was the Federal Circuit's failure to follow its own procedures for hearing cases en banc. According to Petitioner's research, in the last twenty years, it appears that the Federal Circuit has decided cases en banc approximately sixty times, about three times per year. En banc cases are heard so infrequently because such cases are reserved for only "question[s] of exceptional importance." Fed. R. App. P. 35(a)(2). Because these cases are so important, the Federal Circuit's Internal Operating Procedures ("IOP") require the court to tell the public the issues it is deciding en banc so that the public may file amicus briefs regarding those issues. IOP 14.3(c).

There appear to be two reasons why the Federal Circuit Internal Operating Procedures require notice to the public. First, as in this case, decisions by the en banc court may affect thousands of currently issued patents, and thus members of the public who could be affected by those decisions should be allowed to comment before any rules change. Second, decisions by the en banc court as they relate to patent law are generally final, due to

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[2] In addition, as discussed *infra* in section VI, there are important public policy reasons for granting the petition.

the Federal Circuit's exclusive appellate jurisdiction over patent law. Indeed, in the last twenty years, it appears that this Court has granted a petition for *certiorari* from an en banc holding of the Federal Circuit only eight times.

Consequently, the Federal Circuit virtually always announces when it is going to rule en banc to give the public a chance to comment on the issue the Federal Circuit is considering. It is true, however, that its internal operating procedures state that the Federal Circuit is not bound by those procedures. IOP 1. It is also true that this is not the first case where the Federal Circuit *sua sponte* and without notice to the public decided a case related to patent law en banc. Petitioner's research appears to show that there have been two such cases out of the approximately sixty cases decided en banc by the Federal Circuit in the last twenty years.[3] Those cases are *Midwest Industries, Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999) (en banc in part, *overruled on other grounds*), and *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006) (en banc in part). In both cases, there was not a single dissent. Thus, with unanimity on that court, briefs from the public would probably have been an exercise in futility.

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[3] In the last twenty years there also have been a few other cases not related to patent law where it appears that the Federal Circuit *sua sponte* decided cases en banc without previous notice to the public. *See, e.g., In re Violation of Rule 50*, 78 F.3d 574 (Fed. Cir. 1996) (en banc) (deciding, over one dissenter, whether a former law clerk improperly practiced before the Federal Circuit).

Moreover, the issues decided en banc in those cases did not involve a ruling that would virtually invalidate an entire class of patent claims. In *Midwest*, the Federal Circuit decided the limited question that it would use its own law "in resolving questions involving the relationship between patent law and other federal and state law rights." *Midwest*, 175 F.3d at 1358-59. In *DSU*, the Federal Circuit merely clarified that to prove inducement of infringement "[t]he plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." *DSU*, 471 F.3d at 1304.

Thus, there appears to have been exactly *one case* (this case) where the Federal Circuit *sua sponte* decided an important issue of patent law over dissenting judges and did not give the public a chance to brief the issue. Such a procedure, in violation of its own rules, especially in a case where it made thousands of patent claims virtually worthless, was improper. The Court should grant the petition and hear this case so that the holders of those now virtually worthless patent claims will have a chance to comment on this issue.

In addition, not only was the public at large precluded from commenting on this issue, but so was Petitioner. In its briefing to the Federal Circuit, Astellas' main focus was not on whether *Atlantic* was correctly decided because *Scripps* remained "good law." Instead, Astellas focused its main argument on the fact that *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), "sets forth

the proper analysis for interpretation of *all* claims, without making any special exception for product-by-process claims and, thus, there was never any need to choose between *Scripps* and *Atlantic*." Astellas Opening Brief at 3 (emphasis in original).

If the Federal Circuit had followed its own procedures and informed Astellas that it was deciding this issue en banc, Astellas would have never stated that "there was never any need to choose between *Scripps* and *Atlantic*" because obviously the new en banc opinion would, in fact, "choose between *Scripps* and *Atlantic*." Therefore, because the Federal Circuit failed to follow its own procedures, Astellas lost its right to focus its argument on why the en banc court should follow *Scripps* and not *Atlantic*.

II. The En Banc Majority Erred in Deciding that Product-by-Process Claims Are to Be Interpreted Differently for Validity than for Infringement

The most important error in the majority's analysis is the fact that claims are now interpreted differently for validity purposes than for infringement purposes. As Judge Newman explained, a product-by-process claim is now a *product claim* when the Patent Office is deciding whether it is patentable, and is "subject to the requirements of novelty, unobviousness, and all other requirements for new products, independent of how the products can be made." App. 82. But a product-by-process claim is now a "*process claim*[ ] for infringement." *Id.* 82 (emphasis added). Thus,

"[f]or the first time, claims are construed differently for validity and for infringement." *Id.* at 81.

It is one of the oldest maxims in patent law, however, that claims are to be interpreted the same for infringement as for validity. As the Court explained 120 years ago: "That which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (U.S. 1889) (internal quotations omitted). This maxim has been followed repeatedly by the Federal Circuit. *See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("claims are construed the same way for both invalidity and infringement"); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses"); *see also* Donald S. Chisum, *5A Chisum on Patents §18.01* (2007) ("A fundamental tenet of patent law is that a claim must be interpreted consistently for purposes of infringement and validity"). Indeed, one law professor commenting on the majority opinion stated that "[i]t doesn't make sense to have the same claim language mean different things for infringement and validity purposes." Steven Seidenberg, *Process Perils: Ruling Narrows the Protection for Product-by-Process Patents*, Inside Counsel at 23 (Aug. 2009) ("*Process Perils*") (quoting University of Michigan Law professor, Rebecca Eisenberg).

Judge Rader's majority opinion ignores the dissent's argument. But, in his original *Atlantic* opinion, Judge Rader freely admitted that the

Federal Circuit's new rule led to one claim interpretation for validity and another for infringement when he stated that "even though product-by-process claims are limited by and defined by the *process* [for infringement], determination of patentability [validity] is based on the *product* itself." *Atlantic*, 970 F.2d at 845 (emphasis added). He further expounded on this issue in his concurrence to the denial of rehearing en banc in *Atlantic* when he stated that the Supreme Court cases he discussed were not limited to old products because "[i]n its infringement rule, the [Supreme] Court did not presume to address patentability concerns like those in *35 U.S.C. §§ 102* [anticipation], *103* [obviousness]." *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1299, 1303 (Fed. Cir. 1992) (Rader, J., concurring) ("*Atlantic Concurrence*"). That is an incorrect statement of patent law.

The Court does not treat infringement separate from anticipation and obviousness. As the Court held, "[t]hat which infringes, if later, would anticipate, if earlier." *Peters*, 129 U.S. at 537. The majority's new standard for product-by-process claims violates that binding precedent. Now, a product that "anticipate[s], if earlier" because it is the same product described by the product-by-process claims *does not* "infringe if later," if it is made by a different process.[4] Thus, the majority's

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[4] Based on a statutory change, the "classic test" put forth in *Peters* has now changed slightly. The Federal Circuit has explained that the "'classic test' must be modified to: That which would *literally* infringe if later in time anticipates if earlier than the date of invention." *Lewmar Marine, Inc. v.*

new rule for product-by-process claims can lead to absurd results. For example, in some cases, juries must decide whether a defendant's product was made (regardless of the process used) before the critical date of a patent. Under the Court's binding precedent, if the jury decides the product was made before, it anticipates; and if the product was made after, it infringes.[5] But that simple rule has been turned on its head by the rule put forward by the en banc majority. Now, if the product was made by a different process than claimed in the patent, and the jury found the product was made before the critical date, it must also find that the product *anticipates* the patented claim. On the other hand, if the jury found the product was made after the critical date, it must also find that the product *does not infringe* the product-by-process claim.

Long ago, the Court explained that a patent claim is not "a nose of wax which may be turned and twisted in any direction," to be interpreted different ways. *White v. Dunbar*, 119 U.S. 47, 51 (U.S. 1886). Here, the majority opinion renders a patent claim as "a nose of wax," twisting and turning the language of the claim to give it one meaning for infringement and an entirely different meaning for validity. Thus,

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Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added).

[5] This example assumes that the patentee conceived of the invention by the critical date and diligently worked on reducing the invention to practice. *Cf.* 37 C.F.R. § 1.131 (discussing prerequisites for swearing behind a reference that is less than one year before the priority date).

Professor Eisenberg stated that the majority's decision here will not "fly in the long run" due to the fact that claim language now "mean[s] different things for infringement and validity purposes." *Process Perils* at 23. But unfortunately the decision of the en banc court will "fly in the long run" unless the Court grants this petition for *certiorari*. Consequently, the Court should grant the petition for *certiorari* to decide whether it was proper for the Federal Circuit to contradict its binding precedent with its new product-by-process rule.

III. The En Banc Majority Erred in Deciding that There Should Be a Single Rule for Product-by-Process Claims Regardless of Whether the Product Claimed Was Old or New

Judge Newman explained that this Court's precedent firmly recognized "that when the product was old and only the process was a patentable invention, a claim for the 'product of that process' could not cover the old product made by a different process." App. 65. She noted, however, that the majority opinion ignored the difference between old products and new products. *See id.* at 53-54, 67.

Although the majority opinion was also silent on this issue, Judge Rader did address this exact issue in his *Atlantic Concurrence*. In that concurrence, Judge Rader correctly stated that "[a patentee] could not acquire product patent rights under [a claim] by merely adding new process limitations to an old product." *Atlantic Concurrence*,

974 F.2d at 1302. Such a claim would merely be a process claim, not a product-by-process claim.[6]

Where Judge Rader went astray, however, is when he claimed that "any attempt to limit the Supreme Court's rule to cases involving old products fails." *Id.* at 1303. But as discussed *infra*, every case where the Court found that a patented claim was not infringed because the process was not used was either a process claim or involved an old product. There is not a single Supreme Court case that involved a product-by-process claim on a new product. Moreover, Judge Rader's statement ignores over 110 years of precedent. In 1891, the Patent Office explicitly explained that when "an article of manufacture is a *new thing*, . . . and that article cannot be properly defined and discriminated from prior art otherwise than by reference to the process of producing it, a case is presented which constitutes an exception to the rule" that "an article of manufacture should not be defined by the process of producing [it]." *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891) (emphasis added).

In addition, Judge Rader's claim that whether a product is new or old is irrelevant ignores this Court's guidance. Judge Rader did not mention *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141 (1989), the *only* case from the Court that uses the term "product-by-process." The Court stated that

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[6] A process claim may be granted on a process for making an existing product as long as "the product as claimed can be made by another materially different process." *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372, 1375 (Fed. Cir. 2009) (internal quotation omitted).

"[a]s long as the end product of the process is adequately defined and *novel* and nonobvious, a patent in the process may support a patent in the *resulting product*." *Id.* at 159 n.* (emphasis added). Thus, this Court's precedent clearly demonstrates that Judge Rader was wrong when he claimed that whether a product is new or old is irrelevant.

IV. The En Banc Majority Erred in Its Analysis of the Precedent of This Court and Other Courts

Although Judge Rader ignored the most relevant binding precedent from this Court, he claimed that other opinions of this Court compel the holding of the majority. In particular he pointed to *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1877); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222 (1880); *Merrill v. Yeomans*, 94 U.S. 568 (1877); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884) ("BASF"); *The Wood-Paper Patent*, 90 U.S. 566 (1874); *Plummer v. Sargent*, 120 U.S. 442 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938). Although Judge Rader claimed that in each of "these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations," App. at 19, he only provided analysis regarding the *BASF* case. *Id.* at 21.

But Judge Rader's analysis is flawed because *BASF* did *not* involve a product-by-process claim. Judge Rader stated that the product at issue in that case was "artificial alizarine," *id.*, and that "artificial alizarines were known in the prior art." *Id.* at 20.

Thus, the product at issue in *BASF* was not a new product; therefore, the only possible patentable invention would be a new process for making that product.[7] But a "process" patent is not a "product-by-process" patent. In addition, the process claim at issue was found not infringed because "it does not satisfactorily appear that the process . . . will produce the defendants' article to any useful extent, if at all." *BASF*, 111 U.S. at 306. Therefore, *BASF* provides no guidance on the correct interpretation of "product-by-process" claims.[8]

Two other cases that the majority mentioned in passing as supporting its holding are the *Goodyear* cases: *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1877), and *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222 (1880). But as the dissent explains, neither case supports the majority because they were not product-by-process claims, but rather process claims. App. 70.

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[7] Indeed, that was the holding in *BASF*. The product at issue "was an old article. While a new process for producing it was patentable, the product itself could not be patented." *BASF*, 111 U.S. at 311.

[8] Interestingly, BASF was involved in a true product-by-process case the same year that the Court decided *BASF*. *Pickhardt v. Packard*, 22 F. 530 (C.C.S.D.N.Y. 1884). The claim in *Pickhardt* was: "As a new manufacture, the coloring matter . . . obtained from [a process] . . .or by any other method which will produce a like result." *Id.* at 531. The *Pickhardt* court properly found that the defendant infringed that claim because even though there was no evidence regarding the process used by the defendant, any process that "produce[d] like results" to the patented product infringed the claim. *Id.* at 531.

Although the majority's analysis of the *Goodyear* cases is wrong, it is not unprecedented. Apparently, one of the defendants in *Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.*, 259 F. 258 (6th Cir. 1919), made the exact same argument. In *Dunn*, the circuit court used the same reasoning as the *Scripps* court, albeit 62 years earlier, and held that a product-by-process claim is infringed based only on the product being identical, even if the process used is different. That court held that it was irrelevant that "[t]he defendants' product is the result of a two-step wire-cutting process[, even though] plaintiff's patent describes a one-step process for making his product." *Id.* at 263. Moreover, that court explicitly rejected the majority's argument here that the *Goodyear* cases stand for the proposition "that a patent for a product is to be confined to the result of the described process." *Id.* at 261 n.2. Instead that court correctly held (as the dissent explained here) that infringement was not found in the *Goodyear* cases because "*[n]othing* which was not made by the process of vulcanization could be the equivalent of the 'hard rubber or vulcanite' of the claim." *Id.* (emphasis added).

The majority also cited to *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938) as support for its holding. But that case is also irrelevant because, as Judge Newman explained, it "involved no product-by-process claims, but rather claims that recite the properties of the product." App. 75; *accord* Passler, 49 U. Miami L. Rev. at 248 ("the claim in *General Electric* was a product claim").

Moreover, that case actually demonstrates that the majority opinion is directly contrary to the Court's precedent because the Court explicitly stated that "a claim may validly describe a new product with some reference to the method of production." *General Electric,* 304 U.S. at 373. In support of that statement it approvingly cited to two circuit cases, *Dunn* (discussed *supra*) and *Trussell Mfg. Co. v. Wilson-Jones Co.*, 50 F.2d 1027 (2d Cir. 1931), which both had held that product-by-process claims cover the product, and not the process.

In *Trussell*, the defendant argued that the claims were invalid due to "the claims [ ] being of a hybrid character, neither for a product nor for a process, but an attempt to define the article by the method of its manufacture." *Id.* at 1029. That court rejected the defendant's argument because while "an old article cannot be patented by claiming it as the product of a new process . . . if the article is new, it may be patented, and the claim will not be invalidated merely because it describes the article with some reference to the method of producing it." *Id.*

As stated *supra,* the majority opinion included a "laundry-list" of other Supreme Court cases, albeit with no analysis of why those cases are relevant.[9] App. 18-19. The majority did not, however, mention the *only* case from the Court that uses the term

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[9] Judge Newman, in her dissent, ably explains why none of these other Supreme Court cases support the majority's decision, *see* App. 68-77; therefore, Astellas will not repeat her analysis here.

"product-by-process." *Bonito*, 489 U.S. at 159 n.*. In *Bonito*, the Court analogized the Florida statute at issue in that case to a "product-by-process patent." *Id.* It noted that a product-by-process "claim 'is one in which the product is defined at least in part in terms of the method or process by which it is made.'" *Id.* (quoting Donald S. Chisum, *Chisum on Patents* §8.05, 8-67 (1988). The Court then stated that "[a]s long as the end product of the process is adequately defined and novel and nonobvious, a patent in the process may support a patent in the resulting product." *Id.* Thus, when there is "a patent in the resulting product," one who makes such a product (regardless of the process used for making that product), would infringe that product claim. Thus, the majority's opinion cannot be squared with this Court's only direct statement on product-by-process claims.

In addition to Supreme Court cases, the majority also included a few cases from the Court of Customs and Patent Appeals and circuit court cases. Once again, the dissent ably explains why these other cases do not support the majority's opinion, and Astellas will not repeat that analysis here. *See* App. 50-57, 77-80. But Astellas will briefly discuss *In re Bridgeford,* 357 F.2d 679, 683 n.5 (C.C.P.A. 1966). Although cited by the majority, *Bridgeford* directly contradicts the majority's opinion. That court explained that for a product-by-process claim "the invention so defined is a product and not a process." *Id.* at 682. In so holding, that court overruled the suggestion in *In re Freeman,* 166 F.2d 178, 181 (C.C.P.A. 1948), that product-by-process

claims are actually process claims. *Bridgeford,* 357 F.2d at 683 n.6.

Apparently because it did not agree with the holding of *Bridgeford*, the majority found it necessary to belittle the Court of Customs and Patent Appeals by claiming that it was "a court with virtually no jurisdiction to address infringement litigation."[10] App. 23. That statement is incorrect because the C.C.P.A. regularly heard appeals of infringement cases coming from the International Trade Commission and its predecessor tribunals. *See, e.g., In re The Orion Co.,* 71 F.2d 458, 460-65 (C.C.P.A. 1934) (affirming the Tariff Commission's decision to embargo certain products for infringing a U.S. patent); *In re Von Clemm*, 229 F.2d 441, 445 (C.C.P.A. 1955) (affirming "the findings and recommendation of the Tariff Commission" after performing a detailed infringement analysis); *Coleco Indus., Inc. v. Int'l Trade Comm'n*, 573 F.2d 1247, 1257-58 (C.C.P.A. 1978) (affirming the decision of the ITC after performing a detailed infringement analysis); *Astra-Sjuco, A.B. v. Int'l Trade Comm'n*, 629 F.2d 682, 686-88 (C.C.P.A. 1980) (same); *Sealed Air Corp. v. Int'l Trade Comm'n*, 645 F.2d 976, 983-85 (C.C.P.A. 1981) (same).

The majority then claimed to find "ambivalence" in *Bridgeford's* holding because that court stated that "'some courts have construed such

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[10] It is ironic that the majority belittled the Court of Customs and Patent Appeals because the Federal Circuit voluntarily chose to make that court's precedent binding on the Federal Circuit. *South Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (en banc).

claims as covering only a product made by the particular process set forth in the claim and not to the product per se.'" App. 24 (quoting *Bridgeford,* 357 F.2d at 683 n.5). The majority then made the incorrect claim that the term "'some courts'. . . as this court notes en banc, includes the United States Supreme Court and *every circuit* court to consider the question." App. 24 (emphasis added). Not only has the United States Supreme Court not addressed this question but, as shown by *Dunn* and *Trussell*, at least the second and sixth circuits did *not* "construe such claims as covering only a product made by the particular process set forth in the claim." *See Dunn*, 259 F. at 265; *Trussell*, 50 F.2d at 1029.

The majority also quotes *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) for the proposition that "product-by-process claims are limited by and defined by the process." App. 20. But again, although the language used was not as precise at it might have been, *Thorpe* was addressing an old product made by an allegedly new process and its holding was that "[i]f the *product* in the product-by-process claim *is the same* as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *Id.* at 697 (emphasis added). Indeed, this Court rejected the majority's interpretation of *Thorpe*, when it explained that, in *Thorpe*, the "product-by-process patent [was] properly denied where [the] *end result* was indistinguishable from prior art." *Bonito*, 489 U.S. at 159 n.* (emphasis added). Thus, whether the process in the product-by-process claim was a claim limitation was never at issue in *Thorpe.*

As shown above, the case law that the majority cited not only does not support the majority, but instead, it actually supports the dissent. Moreover, this case is much more than the typical disagreements that occur in contested opinions, where the majority describes cases one way, the dissent describes cases the other way, and the petitioner agrees with the dissent. While that is certainly true here, there is an additional factor.

The arguments made by Judge Rader in his majority opinion are virtually identical to the arguments he made in both his *Atlantic* and *Atlantic Concurrence* opinions. *See* App. 17-20 (citing *Atlantic* for its "discussi[on] of each of the [Supreme Court] cases" listed in the en banc opinion and stating that it would "adopt[ ] the rule in *Atlantic*"). Similarly, the arguments that Judge Newman made in her dissent are virtually identical to the arguments in her opinion in *Scripps* and in her dissent from the denial of granting rehearing en banc in *Atlantic*. *Compare* App. 50-60, 66-80 (explaining that the majority's holding is not supported by the Supreme Court cases, the circuit court cases and the C.C.P.A. cases that the majority cites and further explaining that *Bridgeford* and *Thorpe* demonstrate that product-by-process claims cover the product) *with Scripps*, 927 F.2d at 1583 (explaining that *Bridgeford* and *Thorpe* demonstrate that product-by-process claims cover the product) *and Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1279, 1285-93 (Fed. Cir. 1992) (Newman, J., dissenting) (explaining that *Atlantic's* holding is not supported by the Supreme Court cases, the circuit

court cases and the C.C.P.A. cases that *Atlantic* cites and further explaining that *Bridgeford* and *Thorpe* demonstrate that product-by-process claims cover the product).

In the seventeen years since the *Atlantic* opinions, dozens of law review articles have been written about product-by-process claims and the different interpretations of those claims by Judge Rader and Judge Newman. As one commentator explained:

> The *Atlantic* opinion is *problematic* in several respects. First, the *Atlantic* panel took language from Supreme Court and C.C.P.A. opinions *out of context*. . . . [In addition o]ften, the courts have made broad assertions in dicta that are not entirely accurate. The *Atlantic* decision relies heavily on this dicta in concluding that product-by-process claims are limited by the process described therein in all cases. The dicta relied on by the *Atlantic* panel, however, primarily involved claims in which a new process was applied to an old or obvious product. Most of the Supreme Court cases on this issue involved old products which could only be distinguished from the prior art by the method used to create the product. In these situations, the invention is the process, not the product.

Michael J. Schutte, *Patent Law: Controversy in the Federal Circuit Over Product-By-Process Claims – Atlantic Thermoplastics Co. v. Faytex Corp. . . .*, 19 Dayton L. Rev. 283, 307-8 (Fall, 1993) (emphasis added).

Indeed, the majority of commentators agree with Mr. Schutte and find that Judge Newman's analysis is much more accurate, especially when it comes to reviewing the Supreme Court precedent, than is Judge Rader's analysis.[11] Thus, this is not merely a case of "he said/she said" (with the petitioner joining in with "she said"), but rather numerous independent third parties have already

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[11] *See, e.g.*, Passler, 49 U. Miami L. Rev. at 248 ("The Atlantic Thermoplastics analysis of Supreme Court precedent was erroneous."); Brian S. Tomko, Comment, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-By-Process Patents*, 60 Brooklyn L. Rev., 1693, 1726 (Winter, 1995) ("The Supreme Court precedent gathered by Judge Rader does not support the proposition that the Court intended to limit a product-by-process claim's scope to the process and the product made by that process."); Alan I. Cohen, Note, *A Prescription for the Treatment of Product-By-Process Patent Infringement*, 67 St. John's L. Rev. 923, 932 (Fall, 1993) ("the majority in *Atlantic Thermoplastics* failed to differentiate between product-by-process claims in which the product could be defined by its structure or characteristics and those in which it could not"); William E. McGowan, Comment, *Patent Law – Limiting Infringement Protection for Product-by-Process Claims – Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), 27 Suffolk U. L. Rev. 300, 307 (Spring, 1993) ("By failing to make a distinction between [cases discussing old and new products], the *Atlantic* court may have erroneously narrowed the scope of infringement protection of product-by-process claims for novel and non-obvious products.").

weighed in that the majority opinion here is wrong as a matter of law because that opinion is virtually identical to the opinion in *Atlantic*. Consequently, the Court should grant the petition for *certiorari* to decide whether the en banc opinion conflicts with the Court's precedent.

V. The En Banc Decision Necessitated that the Panel Improperly Rewrite the Claims

As both of the dissenting opinions noted, the error in the majority's opinion is further demonstrated by its treatment of the phrase "obtainable by."[12] The two independent claims at issue in this petition are claims 2 and 5, which state:

> 2. Crystalline [cefdinir] which is *obtainable by* acidifying a solution containing [cefdinir] at room temperature or under warming.
>
> 5. Crystalline [cefdinir] which is *obtainable by* dissolving [cefdinir] in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room

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[12] This section of the opinion is not part of the en banc section, but it directly flows from the en banc's ruling, which is why both of the dissents discussed this issue. *See* App. 83-84 (Newman, J., dissenting); App. 88 (Lourie, J., dissenting).

> temperature and allowing the solution to stand.

App. 7 (emphasis added).

The majority opinion simply ignored that the patent claimed cefdinir "which is *obtainable* [by a process]," and instead improperly redefined the claim to cover cefdinir "which is *obtained* [by a process]." *See* App. 29. Here, the "plain import" of the claims could not be more clear. The starting point for claim construction is the words of the claim. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). "Obtainable" has a well-known plain meaning. It is defined, according to Webster's, as "capable of being obtained." Webster's Third New International Dictionary at 1559 (1993). It does not mean "obtained by." The majority, however, contended that it was proper to rewrite "obtainable by" to "obtained by," because otherwise claims 2 through 5 would be duplicative of each other. *See* App. 28. But the majority is incorrect for two reasons. First, "[c]ourts cannot rewrite claim language." *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008). Second, inventors have the right to define their invention how they choose. As the majority noted, it can be difficult to prove infringement for product-by-process claims. Therefore, Astellas chose to claim multiple processes because if a defendant's product was made by any of the claimed processes, there would be few, if any, evidentiary issues regarding infringement. If, on the other hand, the defendant's product was made by a different process, Astellas could still prove infringement if it could show that

the product was the same as the product described in its product-by-process claims. In any event, even if the panel was right that claims 2 and 5 are duplicative of each other, the clear language of the claims "trumps the doctrine of claim differentiation." *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1582 (Fed. Cir. 1997).

Moreover, the Federal Circuit's unilateral decision to decide that "obtainable by" actually means "obtained by" puts thousands of current patents at risk. Indeed, in the last twenty years, Petitioner's research demonstrates that over 11,000 patents have claims that include the phrase "obtainable by."[13] The Court should grant the petition to decide whether it was proper for the Federal Circuit to emasculate product-by-process claims.

VI. Product-by-Process Patents Promote the Progress of Science

The majority opinion claimed that, due to increasingly sophisticated technology, product-by-process claims may no longer be necessary because few structures will be "too complex to analyze." App. 25. That statement is incorrect. Indeed, product-by-

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[13] A search in the Lexis "Utility, Design and Plant Patents" database using the search term "obtainable by" in the segment "claims" for patents issued between August 26, 1989, and August 26, 2009, identified over 11,000 patents with claims including the term "obtainable by." As patent terms are generally twenty years from the date of filing, the vast majority of those patents are still in effect.

process claims are more important now than they have ever been because the "protection provided by product-by-process patents is particularly necessary in the areas of pharmaceuticals and biotechnology, due to the high costs of research and investment." Cohen, 67 St. John's L. Rev. at 936.

Many of the latest chemical claims and biotechnology claims such as "recombinant DNA and molecular purification" can only be patented "by reference to the process used to manufacture [them]--i.e., by using [ ] product-by-process claim[s]." Tomko, 60 Brooklyn L. Rev. at 1698; *see also* Kevin J. McGough and Daniel P. Burke, *A Case for Expansive Patent Protection of Biotechnology Inventions*, 6 Harv. J. Law & Tec. 85, 101 (Fall, 1992) ("Since further innovation will require great expense and laborious research, investors need reasonable assurances that expansive product or product-by-process patent protection will facilitate attractive returns on investment. This is particularly true regarding . . . DNA sequence claims and claims to host cells."). Biotechnology companies may be particularly affected by the majority's holding:

> Given the exorbitant expense incurred in researching and developing new products, the biotechnology industry depends upon patent protection for newly developed pharmaceuticals. Because some products of biotechnology are incapable of independent structural definitions, patentees often opt to claim these products using product-by-process

> language. In *Atlantic* [and by extension the majority's holding here], the Federal Circuit impairs the biotechnology industry's ability to obtain patent protection by narrowly construing the scope of infringement protection of product-by-process claims as applying only to the specific manufacturing process of the drug.

McGowan, 27 Suffolk U. L. Rev. at 308.

Moreover, product-by-process claims have become so important that the FDA now allows product-by-process claims to be listed in the Orange Book for new drugs.[14] Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 Duke L. & Tech. Rev. 18 (Aug. 2003) ("Product-by-process patents are listable in the Orange Book; . . . [provided] that the patent being submitted is a product-by-process patent in which the product claimed is novel, as opposed to the process being novel . . . [because] process patents . . . cannot be submitted for listing"); *see* 21 C.F.R. § 314.53(c)(2)(i)(L) (a product-by-process patent may be listed if "the product claimed is novel").

But the Federal Circuit's decision here contradicts the FDA's decision. The FDA allowed

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[14] The "Orange Book" is the colloquial name given to the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations." Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, Mich. St. L. Rev. 631, 634 (Fall, 2007).

product-by-process claims explicitly because they are claims for products, not processes, as process patents can not be included in the Orange Book. *Id.* Thus, if the Court does not review the decision here, numerous product-by-process patent claims may lose their protection of being listed in the Orange Book.

Finally, Judge Rader's contention that inventors may still "stake claims in product-by-process terms," App. 23, will bring cold comfort to pharmaceutical or biological researchers who have uncovered a new important product, but are not able to accurately describe the structure of that important product. Because the only part of the claim the Federal Circuit will protect is the process, the researchers would most likely file a process claim, rather than what one commentator called "a glorified process patent."[15] *See* Tomko, 60 Brooklyn L. Rev. at 1696 ("the *Atlantic* panel pared the scope of a product-by-process patent to that of a glorified process patent"). Thus, the researchers may lose the fruits of their valuable research when "a competing biotechnology company [ ] pirate[s the] pharmaceutical product patented by a product-by-process claim by slightly altering the method of manufacturing the drug." McGowan, 27 Suffolk U. L. Rev. at 308.

The United States Constitution, Art. I, Sec. 8, Clause 8 maintains that patents "promote the

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[15] Indeed, in some respects, product-by-process claims are less than "glorified process patents" because not only must the patentee prove that the alleged infringer practices the process claimed, but then must also prove that the resulting product is, in fact, the product claimed.

progress of science . . . by securing for limited times to . . . inventors the exclusive right to their . . . discoveries." (Initial Capitalization omitted). "Product-by-process claims fill an important gap in patent law by furnishing an inventor who cannot describe her invention in terms precise enough to gain a conventional product patent with the means to gain the same protection." Tomko, 60 Brooklyn L. Rev. at 1738. Thus, product-by-process patents that provide strong protection for the product described are an important part of "promot[ing] the progress of science." As such, the Court should grant the petition for *certiorari* to decide whether the Federal Circuit's weakening to the point of destroying product-by-process claims complies with the Court's precedent and is in the nation's interest.

CONCLUSION

For the foregoing reasons, the petition for *certiorari* should be granted.

Respectfully submitted,

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APPENDIX

ABBOTT LABORATORIES, Plaintiff-Appellant, and ASTELLAS PHARMA, INC., Plaintiff-Appellant,

v.

SANDOZ, INC., Defendant-Appellee, and SANDOZ GMBH, Defendant, and TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants-Appellees, and RANBAXY LABORATORIES, LTD. and RANBAXY, INC., Defendants, and PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, Defendants. LUPIN LIMITED, Plaintiff/Counterclaim Defendant-Appellee, and LUPIN PHARMACEUTICALS, INC., Counterclaim Defendant-Appellee, v. ABBOTT LABORATORIES, Defendant/Counterclaimant-Appellant, and ASTELLAS PHARMA, INC., Defendant/Counterclaimant-Appellant.

2007-1400, 2007-1446

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

566 F.3d 1282

May 18, 2009, Decided

DISPOSITION: AFFIRMED.

COUNSEL: James F. Hurst, Winston & Strawn LLP, of Chicago, Illinois, argued for all plaintiffs-appellants in 2007-1400 and defendants/counterclaimants-appellants in 2007-1446. With him on the briefs for Abbott Laboratories were Todd J. Ehlman, Kathleen B. Barry, and Ivan M. Poullaos, and Steffen N. Johnson, of Washington, DC. Of counsel on the brief for Abbott Laboratories were William F. Cavanaugh, Jr., Jeffrey I.D. Lewis, and Stuart E. Pollack, Patterson Belknap Webb & Tyler LLP, of New York, New York. Of counsel was John C. Knapp. On the briefs for Astellas Pharma, Inc., were Richard D. Kelly, Stephen G. Baxter and Frank J. West, Oblon, Spivak, McClelland, Maier & Neustadt, P.C., of Alexandria, Virginia.

Meredith Martin Addy, Brinks, Hofer, Gilson & Lione, of Chicago, Illinois, argued for defendant-appellee Sandoz, Inc. With her on the brief were Thomas J. Filarski, Mark H. Remus, C. Noel Kaman, and Laura A. Lydigsen. Of counsel was Rashad L. Morgan.

Thomas J. Meloro, Jr., Wilkie Farr & Gallagher LLP, of New York, New York, argued for defendants-appellees Teva Pharmaceuticals USA, Inc., et al. With him on the brief was Neal K. Feivelson. Of counsel were Michael W. Johnson and Alexander H. Swirnoff.

Deanne M. Mazzochi, Rakoczy Molino Mazzochi Siwik, LLP, of Chicago, Illinois, argued for plaintiff/counterclaim defendant-appellee Lupin Limited

and counterclaim defendant-appellee, Lupin Pharmaceuticals, Inc. in 2007-1446. With her on the brief were William A. Rakoczy, Paul J. Molino, and Amy D. Brody.

JUDGES: Before RADER, PLAGER, and BRYSON, Circuit Judges. MICHEL, Chief Judge, and RADER, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges, have joined Section III.A.2 of the opinion. Dissenting opinion as to Section III.A.2 filed by NEWMAN, Circuit Judge, in which MAYER and LOURIE, Circuit Judges, join. Dissenting opinion filed by LOURIE, Circuit Judge. SCHALL, Circuit Judge, did not participate as a member of the en banc court.

OPINION BY: RADER

OPINION

RADER, *Circuit Judge.*

In this case, the same patent, U.S. Patent No. 4,935,507 (the '507 patent), occasions litigation in both the United States District Court for the Eastern District of Virginia and the United States District Court for the Northern District of Illinois. The Virginia District Court granted the motion of Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively Lupin) for summary judgment of noninfringement. In the other case, the Illinois District Court denied a preliminary injunction to Abbott Laboratories, the exclusive licensee of the '507 patent, based on the claim construction from the Eastern District of Virginia.

Because the Eastern District of Virginia correctly construed the claims of the '507 patent and correctly discerned no genuine issues of material fact on literal infringement of claims 2-5 or infringement by equivalents of claims 1-5, this court affirms its partial summary judgment of noninfringement. Likewise, this court affirms the Northern District of Illinois' denial of Abbott's motion for a preliminary injunction, based in large part on the same correct claim construction.

I.

Abbott Laboratories, the exclusive licensee of the '507 patent, markets crystalline cefdinir according to the '507 patent under the trade name Omnicef. The Virginia case arose when Lupin sought a declaratory judgment of noninfringement against Abbott Laboratories and Astellas Pharma Inc., the owner of the '507 patent (collectively Abbott). The Food and Drug Administration had previously approved Lupin's Abbreviated New Drug Application (ANDA) to market a generic version of Omnicef. Lupin's generic product contains almost exclusively the Crystal B form of crystalline cefdinir (cefdinir monohydrate), whereas Abbott's Omnicef product contains the Crystal A form of crystalline cefdinir (cefdinir anhydrate). Further, Lupin makes its products with processes other than those claimed in the '507 patent. For these reasons, Lupin brought the Virginia action to clarify that its proposed product would not infringe a valid patent. Abbott counterclaimed for infringement. The Eastern District of Virginia construed the claims, *Lupin Ltd. v. Abbott Laboratories*, 484 F. Supp. 2d 448 (E.D. Va. 2007) (*Lupin CC Order*), and

ultimately granted-in-part Lupin's motion for summary judgment of noninfringement, as to both literal and equivalent infringement for claims 2-5 and as to equivalent infringement for claim 1, *Lupin Ltd. v. Abbott Labs.*, 491 F. Supp. 2d 563 (E.D. Va. 2007) (*Lupin SJ Order*). The parties stipulated to the dismissal without prejudice of the remaining claims (invalidity) and counterclaims (literal infringement of claim 1).

In the Illinois action, Abbott sued Sandoz, Inc. and Sandoz GmbH (collectively Sandoz), Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. (collectively Teva), Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical (all defendants, collectively, Sandoz and Teva) for infringement of the '507 patent. Like Lupin, Sandoz and Teva had previously filed ANDAs, seeking to market generic versions of Omnicef. Abbott sought a preliminary injunction in the Illinois case. For purposes of that motion, the parties agreed to adopt the Eastern District of Virginia's claim construction from the *Lupin* case. *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767 (N.D. Ill. 2007) (*Sandoz PI Order*). Despite this agreement, the parties to the *Sandoz* case disagreed as to how to interpret some of the Eastern District of Virginia's constructions, necessitating some clarification by the Northern District of Illinois. 486 F. Supp. 2d at 770-71 (disputing "Crystal A," "peaks," and "about," and seeking construction of "powder X-ray diffraction pattern," which the Eastern District of Virginia had not defined). Ultimately, the Northern District of Illinois, based on the claim

construction from Virginia, denied the preliminary injunction.

Both cases arrived at this court on appeal. This court heard the cases together and decides them together with this decision.

II.

The '507 patent has five claims, all of which Abbott asserts against Lupin as well as Sandoz and Teva. Claim 1 claims crystalline cefdinir, using its chemical name, and defining its unique characteristics with powder X-ray diffraction (PXRD) angle peaks:

> 1. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem.-4-carboxylic acid (syn isomer) which shows the peaks at the diffraction angles shown in the following table in its powder X-ray diffraction pattern:
>
> | diffraction angle [degree] |
> | --- |
> | about 14.7 [degrees] |
> | about 17.8 [degrees] |
> | about 21.5 [degrees] |
> | about 22.0 [degrees] |
> | about 23.4 [degrees] |
> | about 24.5 [degrees] |
> | about 28.1 [degrees] |

'507 patent, col.16 ll.13-27. In contrast, claims 2-5 claim crystalline cefdinir, without any PXRD peak limitations, but with descriptions of processes used to obtain the crystalline cefdinir. Claims 2 and 5 are independent:

> 2. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by acidifying a solution containing 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) at room temperature or under warming.
>
> 5. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by dissolving 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

Id. at col.16 ll.29-34, 43-50.

These claims use PXRD as a way to claim the structure and characteristics of the unique crystalline form. PXRD is a method for identifying and distinguishing different crystalline compounds. The method beams X-rays toward a powdered chemical. The method then measures the ways the rays reflect or bend upon contact with the chemical. The diffrac-

tion angles and intensities vary with the type and purity of the test compound. A graph then plots the diffraction angle on one axis and the intensity on another. These graphs yield a unique "fingerprint" for each crystalline form of a chemical. A more sensitive form of X-ray diffraction is single crystal X-ray diffraction (SCXRD). As this name suggests, this method uses only a single crystal as a sample. SCXRD does not detect intensity, but produces a more precise diffraction angle measurement.

The '507 patent was not the first cefdinir patent. Rather, Astellas' prior art U.S. Patent No. 4,559,334 (the '334 patent) describes the discovery of cefdinir as a compound demonstrating high antimicrobial activity. *'334 patent*, col.11 ll.18-24. The *'334 patent* expired on May 6, 2007.

The '507 patent claims priority to Japanese Patent Application No. 62-206199 (the JP '199 application), which claimed two crystalline forms of cefdinir, "Crystal A" and "Crystal B." The JP '199 application claimed Crystals A and B very specifically, defining Crystal A by three infrared (IR)-absorption wavelengths and sixteen PXRD angles and intensities. In contrast, Crystal B featured five IR-absorption wavelengths and twenty-one PXRD angles/intensities.

Despite using the JP '199 application for priority, the '507 patent's specification differs significantly. Specifically, Abbott (actually Fujisawa Pharmaceutical Co., Ltd., Astellas' predecessor in interest) jettisoned the Crystal B disclosure found in the JP '199 application and crafted broader claims in its prosecution of the '507 patent. Because the JP '199 appli-

cations defines Crystal A and Crystal B physiochemically rather than structurally, the forms actually represent subgenuses of crystalline cefdinir. Thus Crystals A and B comprise crystalline forms of varying structures, which in the context of this case means varying levels of hydration.

The Eastern District of Virginia construed the claim terms "crystalline," "shows," "peaks," and "about" as follows:

> 1) "crystalline" means "Crystal A as outlined in the specification";
>
> 2) "shows" requires the display of a powder X-ray diffraction pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display;
>
> 3) "peaks" is the plural of "peak;" a "peak exists at a powder X-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and followed by powder X-ray diffraction angle with a lower intensity measurement; "noise" refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test;

> 4) "about" encompasses measurement errors inherently associated with powder X-ray diffraction testing.

Lupin CC Order, 484 F. Supp. 2d at 459, 466. The Eastern District of Virginia also concluded that claims 2-5 were product-by-process claims. *Id.* Later the district court concluded that the process terms of claims 2-5, indicated by the phrase "obtainable by," limit the claims to the specified processes and process steps. In reaching that conclusion, the trial court followed this court's opinion in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992). *Lupin SJ Order*, 491 F. Supp. 2d at 567-68; *Lupin Ltd. v. Abbott Labs.*, No. 3:06-CV-400 (E.D. Va. May 10, 2007) (*Lupin PbyP Order*). In the *Lupin* appeal, Abbott challenges only the Eastern District of Virginia's constructions of "crystalline" and "obtainable by."

III.

Evaluation of a summary judgment of noninfringement requires two steps: claim construction, which this court reviews without deference, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1451 (Fed. Cir. 1998) (en banc), and comparison of the properly construed claims to the accused product, process, or composition of matter, which in the context of summary judgment also occurs without deference, *see Ormco Corp. v. Align Technologies, Inc.*, 498 F.3d 1307, 1312 (Fed. Cir. 2007). Although infringement by equivalency is a question of fact, this court may affirm summary judgment "where no reasonable fact finder could find equivalence." *Sage*

Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed. Cir. 1997) (citing *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 39 n.8, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997).

A. Claim Construction

Because the claims define the patent right, *see Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004), naturally "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). But the claims "must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995)* (en banc), *aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996).* A patent's specification provides necessary context for understanding the claims, and "is always highly relevant to the claim construction analysis." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). While equally true in a general sense, sometimes the specification offers practically incontrovertible directions about claim meaning. For example, inventors may act as their own lexicographers and give a specialized definition of claim terms. *See id.* at 1316. Likewise, inventors and applicants may intentionally disclaim, or disavow, subject matter that would otherwise fall within the scope of the claim. *See id.*

When consulting the specification to clarify the meaning of claim terms, courts must take care not to import limitations into the claims from the specifica-

tion. This court has recognized the "fine line between" the encouraged and the prohibited use of the specification. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). When the specification describes a single embodiment to enable the invention, this court will not limit broader claim language to that single application "unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)). By the same token, the claims cannot "enlarge what is patented beyond what the inventor has described as the invention." *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1140 (Fed. Cir. 2003) (quoting *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001)). Thus this court may reach a narrower construction, limited to the embodiment(s) disclosed in the specification, when the claims themselves, the specification, or the prosecution history clearly indicate that the invention encompasses no more than that confined structure or method. *See Liebel-Flarsheim*, 358 F.3d at 908.

Along with the specification, the prosecution history is "intrinsic evidence" of the meaning of the claims, because it "provides evidence of how the [United States Patent & Trademark Office (PTO)] and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. Although often producing ambiguities occasioned by ongoing negotiations between the inventor and the PTO, "the prosecution history can often inform the meaning of the claim language

by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* "[C]lear and unmistakable" statements during prosecution may also disavow claim scope. *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008) (quoting *Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006)).* Again owing in part to the inherent ambiguities of prosecution history, the doctrine of prosecution disclaimer only applies to unambiguous disavowals. *See id.* at 1375.

1. "crystalline"

The Eastern District of Virginia's construction of "crystalline" in claims 1-5 as "Crystal A" included the important caveat "as outlined in the specification." *Lupin CC Order*, 484 F. Supp. 2d at 459. Although the Eastern District noted the parties agreed that "crystalline" ordinarily means exhibiting "uniformly arranged molecules or atoms," *id.* at 454, the court relied on the language of the claims themselves, the specification, and the prosecution history to arrive at the more specific meaning recited in the specification.

The '507 specification states that "Crystal A of the compound (I) [cefdinir] shows its distinguishing peaks" at the seven particular PXRD angles enumerated in claim 1. 507 *patent* col.1 ll.51-62. Indeed, the phrase "Crystal A of the compound (I)" appears throughout the written description, and the patent offers the following definition: "any crystal of the compound (I) which shows substantially the

same diffraction pattern [as in the table in col.1/claim 1] is identified as Crystal A of the compound (I)." *Id.* at col.1 l.67-col.2 l.2. As the Eastern District correctly concluded:

> Had Astellas intended, in the chart found in column 1, to distinguish Crystal A from other forms of crystalline cefdinir that also fall within the scope of claim 1, it would have listed, at a minimum, an eighth peak associated only with Crystal A. However, by listing in column 1 only the same seven 'distinguishing' peaks featured in Claim 1, Astellas confirmed that Crystal A was synonymous with the invention listed in Claim 1.

Lupin CC Order, 484 F. Supp. 2d at 456-57. The problem, within the confines of claim 1, is that defining "crystalline" as "Crystal A," where "Crystal A" incorporates the seven PXRD peak limitations, arguably renders the remainder of that claim redundant. To distinguish the invention, however, the specification refers several times to "Crystal A of the compound (I) of the present invention," *see, e.g.*, '507 patent, col.2 ll.15-17, and offers no suggestion that the recited processes could produce non-Crystal A compounds, even though other types of cefdinir crystals, namely Crystal B, were known in the art. As noted earlier, the Crystal B formulation actually appears in the parent JP '199 application. Thus, Abbott knew exactly how to describe and claim Crystal B compounds. Knowing of Crystal B, however, Abbott chose to claim only the A form in the '507 patent. Thus, the trial court properly limited the term

"crystalline" to "Crystal A." The trial court's definition correctly identifies claim 1's literal scope.

Unlike claim 1, claims 2-5 do not recite the seven PXRD peaks expressly associated with Crystal A in the '507 specification. Nonetheless, the Eastern District of Virginia limited "crystalline" to "Crystal A" in these claims as well, The trial court gave two reasons for this limitation. First, "[t]he process steps detailed in those claims [claims 2-5] correspond with the processes for making Crystal A disclosed in the specification under the heading 'The Process For Preparing Crystal A of The Compound (I).'" *Id.* at 457 (quoting '507 patent, col.2 ll.13-14). Second, the parent JP '199 application recited these steps "to distinguish between preparations of Crystal A and Crystal B." *Id.* (citing JP '199 application, col.6 ll.1-25).

In limiting "crystalline" to "Crystal A" in claims 1-5, the Eastern District of Virginia did not improperly import the preferred embodiment into the claims. Initially, Crystal A is the only embodiment described in the specification. As discussed above, the specification's recitation of Crystal A as its sole embodiment does not alone justify the trial court's limitation of claim scope to that single disclosed embodiment. *See Liebel-Flarsheim*, 358 F.3d at 906 ("[T]his court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). In this case, however, the rest of the intrinsic evidence, including the prosecution history and the priority JP '199 application, evince a clear intention to limit the '507 patent

to Crystal A as defined by the seven PXRD peaks in the specification and in claim 1.

Initially, the Eastern District of Virginia properly considered the JP '199 application as relevant objective evidence of the inventor's knowledge at the filing of the '507 patent. While statements made during prosecution of a foreign counterpart to a U.S. patent application have a narrow application to U.S. claim construction, *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006), in this case the JP '199 application is part of the prosecution history of the '507 patent itself. Indeed the *'507 patent* claims priority from the JP '199 application. Furthermore, the trial court did not rely on attorney argument or amendments during a foreign prosecution as in *Pfizer*, but consulted only the contents of the foreign priority application. The JP '199 application strongly suggests that the '507 patent intentionally excluded Crystal B compounds. As discussed above, the JP '199 application establishes unequivocally that Abbott knew and could describe both Crystal A and Crystal B. Abbott could have retained the disclosure of Crystal B to support the broader claims of the '507 patent, but instead disclosed and claimed A alone.

Furthermore, the prosecution history of the '507 patent shows a clear and intentional disavowal of claim scope beyond Crystal A. Co-inventor Takao Takaya, who prepared samples according to Examples 14 and 16 of the prior art '334 patent and a sample of "Crystal A of the present application," offered a declaration that Crystal A was more stable than the prior art samples from the '334 patent. An analytical chemist, Yoshihiko Okamato, corroborated

this evidence. J. A. 501-04. Beyond these declarations, the applicant specifically limited the invention to Crystal A: "the *method of preparation* of the crystalline form of the presently claimed compounds is not considered the heart of the present invention. The crystalline form of the compound represents the inventive concept hereof, and it is clear that [the '334 patent] does not anticipate or suggest said crystalline form." J. A. 511 (Response to Office Action of May 11, 1989, received October 27, 1989, at 6).

Given the exclusive focus on Crystal A in the specification as well as the prosecution history of the '507 patent, the Eastern District of Virginia properly limited "crystalline" in claims 1-5 to "Crystal A."

2. proper interpretation of product-by process claims[1]

This court addresses Part III.A.2 of this opinion en banc, which addresses the proper interpretation of product-by-process claims in determining infringement.

Claims 2-5 of the '507 patent begin by reciting a product, crystalline cefdinir, and then recite a series of steps by which this product is "obtainable." The Eastern District of Virginia correctly categorized claims 2-5 as product-by-process claims. On appeal,

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[1] This court, *sua sponte*, took en banc Section III.A.2 before issuing a panel opinion. The following judges join this section of the opinion: Chief Judge Michel and Judges Rader, Bryson, Gajarsa, Linn, Dyk, Prost, and Moore. Judges Newman and Lourie dissent in separate opinions. Judges Mayer and Lourie join in Judge Newman's dissent. Judge Schall did not participate as a member of the en banc court.

Abbott argues that the Eastern District erred in construing the process steps of claims 2-5 under the rule in *Atlantic Thermoplastics*, 970 F.2d at 846-47, that "process terms in product-by-process claims serve as limitations in determining infringement," rather than in accordance with *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("[T]he correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims."). This court takes this opportunity to clarify en banc the scope of product-by-process claims by adopting the rule in *Atlantic Thermoplastics*.

In *Atlantic Thermoplastics*, this court considered the scope of product-by-process claim 26 in the patent at issue: "[t]he molded innersole produced by the method of claim 1." 970 F.2d at 836. The patentee urged that competing, indistinguishable innersoles made by a different method nonetheless infringed claim 26. *Id. at 838.* This court rejected the patentee's position. This court in *Atlantic Thermoplastics* construed product-by-process claims as limited by the process. Id. at 846-7.

This rule finds extensive support in Supreme Court opinions that have addressed the proper reading of product-by-process claims. *See Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493, 23 L. Ed. 952, 1877 Dec. Comm'r Pat. 171 (1877) ("The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed."); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224, 26 L. Ed. 149, 1881 Dec. Comm'r Pat. 131 (1880) ("[T]o constitute infringement of the patent, both the material of which

the dental plate is made . . . and the process of constructing the plate . . . must be employed."); *Merrill v. Yeomans,* 94 U.S. 568, 24 L. Ed. 235, 1877 Dec. Comm'r Pat. 279 (1877); *Cochrane v. Badische Anilin & Soda Fabrik,* 111 U.S. 293, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1884) (BASF); *The Wood-Paper Patent,* 90 U.S. 566, 596, 23 L. Ed. 31 (1874); *Plummer v. Sargent,* 120 U.S. 442, 7 S. Ct. 640, 30 L. Ed. 737 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.,* 304 U.S. 364, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 (1938); *see also Atl. Thermoplastics,* 970 F.2d at 839-42 (discussing each of these cases). In these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations. In addition, the binding case law of this court's predecessor courts, the United States Court of Customs and Patent Appeals (*see In re Hughes,* 496 F.2d 1216, 1219 (CCPA 1974) (acknowledging that "true product claims" are "broader" in scope than product-by-process claims)), and the United States Court of Claims (*see Tri-Wall Containers v. United States,* 408 F.2d 748, 751, 187 Ct. Cl. 326 (Ct. Cl. 1969)), followed the same rule.

This court's sister circuits also followed the general rule that the defining process terms limit product-by-process claims. *See, e.g., Hide-Ite Leather v. Fiber Prods.,* 226 F. 34, 36 (1st Cir. 1915) ("It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process."); *Paeco,*

Inc. v. Applied Moldings, Inc., 562 F.2d 870, 876 (3d Cir. 1977) ("A patent granted on a product claim describing one process grants no monopoly as to identical products manufactured by a different process."). Indeed, this court itself had articulated that rule: "For this reason, even though *product-by-process claims are limited by and defined by the process*, determination of patentability is based on the product itself." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (emphasis added).

The Supreme Court has long emphasized the limiting requirement of process steps in product-by-process claims. In *BASF*, the Court considered a patent relating to artificial alizarine. Specifically, the patent claimed "[a]rtificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result." 111 U.S. at 296 (quoting U.S. Patent Reissue No. RE 4,321). In turn, the specification generally described a method for making artificial alizarine involving anthracine or its derivatives. Alizarine had been in use for thousands of years as a red textile dye, traditionally extracted from madder root. Pure alizarine has the chemical formula C[14]H[8]O[4], but "artificial alizarines" available in the market at the time of the litigation varied from almost completely pure alizarine, to combinations of alizarine and anthrapurpurine, to pure purpurine containing no alizarine whatsoever. *Id.* at 309-10. The defendant's product contained approximately sixty percent anthrapurpurine. Thus both alizarine and artificial alizarines were known in the prior art. The Supreme Court clearly articulated some of the scope and validity problems that

arise when process limitations of product-by-process claims are ignored:

> [The defendant's product] is claimed by the plaintiff to be the artificial alizarine described in No. 4,321, and to be physically, chemically, and in coloring properties similar to that. But what that is is not defined in No. 4,321, except that it is the product of the process described in No. 4,321. Therefore, unless it is shown that the process of No. 4,321 was followed to produce the defendant's article, or unless it is shown that that article could not be produced by any other process, the defendant's article cannot be identified as the product of the process of No. 4,321. Nothing of the kind is shown.
>
> * * *
>
> If the words of the claim are to be construed to cover all artificial alizarine, whatever its ingredients, produced from anthracine or its derivatives by methods invented since Graebe and Liebermann invented the bromine process, we then have a patent for a product or composition of matter which gives no information as to how it is to be identified. *Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.*

Id. at 310 (emphasis added).

After *BASF*, the Supreme Court continued to emphasize the importance of process steps in evaluating the infringement of product-by-process claims. *See, e.g., Plummer*, 120 U.S. at 448 ("[W]hatever likeness that may appear between the product of the process described in the patent and the article made by the defendants, their identity is not established unless it is shown that they are made by the same process."); *Gen. Elec. Co.*, 304 U.S. at 373 ("[A] patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced." (footnote omitted)).

Thus, based on Supreme Court precedent and the treatment of product-by-process claims throughout the years by the PTO and other binding court decisions, this court now restates that "process terms in product-by-process claims serve as limitations in determining infringement." *Atl. Thermoplastics*, 970 F.2d at 846-47. As noted earlier, this holding follows this court's clear statement in *In re Thorpe* that "product by process claims are limited by and defined by the process." 777 F.2d at 697.

More recently, the Supreme Court has reiterated the broad principle that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkinson*, 520 U.S. at 19. Although *Warner-Jenkinson* specifically addressed the doctrine of equivalents, this rule applies to claim construction overall. As applied to

product-by-process claims, *Warner-Jenkinson* thus reinforces the basic rule that the process terms limit product-by-process claims. To the extent that *Scripps Clinic* is inconsistent with this rule, this court hereby expressly overrules *Scripps Clinic*.

The dissenting opinions lament the loss of a "right" that has never existed in practice or precedent -- the right to assert a product-by-process claim against a defendant who does not practice the express limitations of the claim. This court's en banc decision in no way abridges an inventor's right to stake claims in product-by-process terms. Instead this decision merely restates the rule that the defining limitations of a claim -- in this case process terms -- are also the terms that show infringement.

Thus this court does not question at all whether product-by-process claims are legitimate as a matter of form. The legitimacy of this claim form was indeed a relevant issue in the nineteenth century when *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891), and some later cases were before the Commissioner of Patents. However, this court need not address that settled issue. The issue here is only whether such a claim is infringed by products made by processes other than the one claimed. This court holds that it is not.

The jurisprudence of the Court of Customs and Patent Appeals -- a court with virtually no jurisdiction to address infringement litigation -- can shed little light on the enforcement of the only claim limitations that an applicant chooses to define the invention. Indeed, this court's venerable predecessor ex-

pressed its ambivalence towards the relevant infringement analysis:

> The policy of the Patent Office in permitting product-by-process type claims to define a patentable product, where necessary, has developed with full cognizance of the fact that in infringement suits some courts have construed such claims as covering only a product made by the particular process set forth in the claim and not to the product per se.

In re Bridgeford, 357 F.2d 679, 683 n.5, 53 C.C.P.A. 1182 (CCPA 1966). The reference to "some courts" in this prior citation, as this court notes en banc, includes the United States Supreme Court and every circuit court to consider the question, including this circuit. *See also* Jon S. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. Pat. Off. Soc'y 528, 530 (1960) ("[P]roduct-by-process claims have met with a most strict interpretation in the courts in infringement proceedings . . . . [T]he courts uniformly hold that only a product produced by the claim-designated process may be held to infringe the claim.") (citing *Gen. Elec. Co.*, 304 U.S. 364, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 and *BASF*, 111 U.S. at 310).

Product-by-process claims, especially for those rare situations when products were difficult or impossible to describe, historically presented a concern that the Patent Office might deny *all* product protection to such claims. *See In re Butler*, 37 F.2d 623, 17

C.C.P.A. 810, 813, 1930 Dec. Comm'r Pat. 187 (CCPA 1930) ("Process claims are valuable, and appellant thinks he is entitled to them; but it is submitted that he should not be limited to control of the process when the article which that process produces is new and useful."). In the modern context, however, if an inventor invents a product whose structure is either not fully known or too complex to analyze (the subject of this case -- a product defined by sophisticated PXRD technology -- suggests that these concerns may no longer in reality exist), this court clarifies that the inventor is absolutely free to use process steps to define this product. The patent will issue subject to the ordinary requirements of patentability. The inventor will not be denied protection. Because the inventor chose to claim the product in terms of its process, however, that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor.

This court's rule regarding the proper treatment of product-by-process claims in infringement litigation carries its own simple logic. Assume a hypothetical chemical compound defined by process terms. The inventor declines to state any structures or characteristics of this compound. The inventor of this compound obtains a product-by-process claim: "Compound X, obtained by process Y." Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. But how would the courts ascertain that the alleged infringer's compound is really the same as the patented compound? After all, the patent holder

has just informed the public and claimed the new product solely in terms of a single process. Furthermore, what analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way?

In sum, it is both unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made. Such a rule would expand the protection of the patent beyond the subject matter that the inventor has "particularly point[ed] out and distinctly claim[ed]" as his invention, 35 U.S.C. § 112 P 6.

Thus, the Eastern District of Virginia correctly applied the rule that the recited process steps limit the product-by-process claims 2-5 for any infringement analysis.

3. "*obtainable* by"

In this case, Abbott's plain language argument, that "*obtainable* by" introduces an optional process, even if "*obtained* by" would introduce limiting process steps, is also unavailing. The *BASF* case, an analogous situation to this case, controls. As noted above, the Supreme Court in *BASF* considered the following claim language: "Artificial alizarine, pro-

duced from anthracine or its derivatives by either of the methods herein described, *or by any other method which will produce a like result.*" *111 U.S.* at 296 (emphasis added). The patentee argued that even though the defendant did not make artificial alizarine by "either of the methods herein described," the claim should capture the product because of the "or by another method" language. *Id.* at 309. The Supreme Court refused to attach importance to those expansive words: "No. 4,321 furnishes no test by which to identify the product it covers, except that such product is to be the result of the process it describes." *Id.* at 305. Abbott's claims 2-5, like those in *BASF* and like product-by-process claims in general, do not furnish any test by which to identify the cefdinir crystals except that they are the result of their respectively claimed processes. As per *BASF*, Abbott's claim cannot capture a product obtained by or obtainable by processes other than those explicitly recited in the claims.

If this court were to strip the process elements from the claims, as Abbott would urge, for infringement purposes, there would then be nothing to differentiate independent claim 2 from independent claim 5. After all, if those claims are not bound by the process terms but only "define" the basic cefdinir compound, then each of the claims recite the same thing, over and over again. Though Abbott argues that it merely intends to give meaning to the word "obtainable," it instead seeks to have this court render meaningless the explicit process limitations that the applicant chose to define its invention.

The intrinsic evidence in this case further rebuts Abbott's contention that its claims are not limited to

those products actually obtained by the processes recited. In column 2 of the '507 patent, under the title heading "The Process for Preparing Crystal A of the Compound (I)," the patentee used specific language to describe the very two processes that are mirrored in claims 2 and 5. '507 patent col.2 ll.13-51. This language is not open-ended, nor does it constitute a mere description of the product by reference to the manner in which it can be made, as Abbott argues. By drafting claims 2 and 5 to incorporate these specific processes, Abbott made a conscious choice to place process requirements on its claimed product. If Abbott had wanted to obtain broader coverage for crystalline cefdinir devoid of any process limitations, as it seeks to do here, it could have simply done so (if indeed, as it argues, it is really the product that is the heart of the invention, not the process). But it did not. The crystals of claims 2 and 5 are simply not identifiable other than by the processes disclosed in column 2. This court must enforce the ways and terms that a party chooses to define its invention.

The prosecution history also does not support Abbott's contention that "obtainable by" offers merely an optional set of definitional process conditions. During prosecution, Abbott faced obviousness rejections based on application claims 6-9, which were process claims that mirrored the *very* process limitations of issued claims 2-5. The PTO refused to issue the claims until one set of duplicates was cancelled. Abbott's action in cancelling claims 6-9 demonstrates its acquiescence to the PTO's view that the process elements of claims 2-5 are critical parts of those claims. In addition, in a response to the PTO's office action, Abbott chose to differentiate a cited §

103 reference, Takaya, on the basis that Abbott's claimed processes are different. For these reasons, the applicant's statement in the file wrapper that "the method of preparation . . . is not considered the heart of the present invention" should not be afforded undue gravitas. The process limitations cannot be haphazardly jettisoned for an infringement analysis when they were so important in the patentability analysis.

In sum, a patentee's use of the word "obtainable" rather than "obtained by" cannot give it a free pass to escape the ambit of the product-by-process claiming doctrine. Claims that include such ambiguous language should be viewed extremely narrowly. If this court does not require, as a precondition for infringement, that an accused infringer actually use a recited process, simply because of the patentee's choice of the probabilistic suffix "able," the very recitation of that process becomes redundant. This would widen the scope of the patentee's claims beyond that which is actually invented--a windfall to the inventor at the expense of future innovation and proper notice to the public of the scope of the claimed invention. For all the above reasons, the Eastern District of Virginia correctly construed the process limitations beginning with "obtainable by" in claims 2-5 as limiting the asserted claims to products made by those process steps.

B. Summary Judgment

In the *Lupin* case, the Eastern District of Virginia granted summary judgment of noninfringement of claims 2-5, both literal and by equivalents, and of claim 1 by equivalents. *Lupin SJ Order*. Lit-

eral infringement of claim 1, i.e., whether Lupin's generic cefdinir product contains any Crystal A, is therefore not a live issue on appeal. As for claims 2-5, the Eastern District noted that "Abbott and Astellas have conceded that literal infringement of Claims 2-5 cannot be established if the product-by-process analysis is performed pursuant to *Atlantic Thermoplastics*," given that "Abbott and Astellas have presented no evidence that Lupin is practicing the process steps set forth in Claims 2-5." *Lupin SJ Order*, 491 F. Supp. 2d at 568. Because the Eastern District correctly applied the rule from *Atlantic Thermoplastics* and likewise properly construed the limiting process terms in claims 2-5, only infringement by equivalents of claims 1-5 remains before this court.

Infringement analysis under the doctrine of equivalents proceeds element-by-element; a generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement. *See Warner-Jenkinson*, 520 U.S. at 29 ("the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole"). The primary test for equivalency is the "function-way-result" or "triple identity" test, whereby the patentee may show an equivalent when the accused product or process performs substantially the same function, in substantially the same way, to achieve substantially the same result, as disclosed in the claim. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 70 S. Ct. 854, 94 L. Ed. 1097, 1950 Dec. Comm'r Pat. 597 (1950). But, because "[d]ifferent linguistic frameworks may be more suitable to different cases," *Warner-Jenkinson*, 520 U.S.

at 40, the function-way-result test is not the only test for equivalency. Equivalency may also be proven where the differences between the invention as claimed and the accused product or process are insubstantial. *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1517-18 (Fed. Cir. 1995) (en banc), rev'd on other grounds, 520 U.S. 17, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997). In no case, however, may the doctrine of equivalents ignore the individual claim elements. *See Warner-Jenkinson*, 520 U.S. at 40 (requiring "a special vigilance against allowing the concept of equivalence to eliminate completely any such [individual] elements").

Because "crystalline" in claims 1-5 is limited to "Crystal A" as defined by the seven PXRD peaks enumerated in claim 1 and in the specification of the '507 patent, the doctrine of equivalents cannot capture crystals that are not themselves equivalent to Crystal A. In turn, the bounds of Crystal A equivalents cannot ignore the limits on Crystal A in the '507 patent, which as discussed above, includes a conscious decision to distinguish Crystal B from the claimed invention. To recall, the applicant removed Crystal B from the U.S prosecution of the parent JP '199 application. The '507 patent indisputably describes and claims Crystal A, and not Crystal B. The *'507 patent*, of course, could have claimed the known Crystal B formulation which was known to the inventors because it appeared in their priority JP '199 application. The applicants chose not to claim Crystal B. Thus Crystal B compounds, most relevantly cefdinir monohydrate, fall outside the scope, literal or equivalent, of claims 1-5 of the '507 patent.

The parties agree that the "bulk" of Lupin's cefdinir product is Crystal B, not Crystal A. The degree to which Lupin's product may or may not also contain Crystal A is the central inquiry regarding the alleged literal infringement of claim 1, which is not part of the present appeal. Abbott cannot extend its exclusive right in the '507 claims under the doctrine of equivalents to embrace known but unclaimed subject matter. In other words, Abbott effectively disclaimed Crystal B during prosecution of the '507 patent, by removing the Crystal B disclosure from the parent JP '199 application and emphasizing the sole teaching of Crystal A in communications with the PTO as well as in the '507 specification itself. Abbott cannot now recapture that unclaimed subject matter under the doctrine of equivalents because the Eastern District properly interpreted claims 2-5 to limit "crystalline" to Crystal A. To expand that claim term to embrace Crystal B would ignore the specific claim limitations of the '507 patent.

Alternatively this court notes that this case seems to fit within the dedication doctrine that forecloses invocation of the doctrine of equivalents. The patent applicant clearly knew of the Crystal B forms of the claimed invention because it claimed and disclosed them in its Japanese priority application. Yet it declined to claim an embodiment expressly disclosed in its priority document, thus dedicating that embodiment to the public and foreclosing any recapture under the doctrine of equivalents. *See Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002).

During prosecution, Abbott chose to eschew Crystal B and focus exclusively on Crystal A compounds.

Without a complete record and no arguments about validity before this court on appeal, this court cannot speculate on the reasons for this choice. Nonetheless, the parties hotly contest whether Example 14, which reports obtaining "crystals" not specifically identified or described, and/or Example 16 of the '334 patent enable cefdinir monohydrate, i.e. Crystal B type crystals.

Beyond the attempt to reinflate the claims to encompass Crystal B based on mathematical comparisons of the PXRD peak patterns of Crystal A and Crystal B, Abbott also asserts that Lupin effectively admitted infringement by equivalents when it claimed before the Food and Drug Administration that its cefdinir generic was a bioequivalent to Abbott's Omnicef product. While bioequivalency may be relevant to the function prong of the function-way-result test, bioequivalency and equivalent infringement are different inquiries. Bioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes. In contrast, equivalency for purposes of patent infringement requires an element-by-element comparison of the patent claim and the accused product, requiring not only equivalent function but also equivalent way and result. Different attributes of a given product may thus be relevant to bioequivalency but not equivalent infringement, and vice versa. As the Northern District of Illinois observed in the *Sandoz* case, "[i]f bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of a patent." *Sandoz PI Order*, 486 F. Supp. 2d at 776. Thus, while potentially relevant,

the bioequivalency of an accused product with a product produced from the patent at issue is not sufficient to establish infringement by equivalents.

Because Crystal B is not an equivalent of Crystal A, the Eastern District of Virginia did not err in granting summary judgment of noninfringement of claims 2-5, both with respect to literal and equivalent infringement, and with respect to equivalent infringement of claim 1.

IV.

This court reviews the grant or denial of a preliminary injunction for abuse of discretion. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). A district court may enter a preliminary injunction based on its consideration of four factors: "(1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest." *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1353-54 (Fed. Cir. 2008) (quoting *PHG Techs., LLC v. St. John Cos., Inc.*, 469 F.3d 1361, 1365 (Fed. Cir. 2006)).

Sandoz and Teva's Omnicef generic products, like Lupin's, are also at least primarily cefdinir monohydrate, a Crystal B compound. *Sandoz PI Order*, 486 F. Supp. 2d at 769. Before the Northern District of Illinois, the parties to the *Sandoz* litigation disputed whether Sandoz and Teva's products also contained small amounts of cefdinir anhydrate, i.e., Crystal A, which would fall within the literal scope of claim 1 of the '507 patent. Working primarily from the East-

ern District of Virginia's claim construction, to which the parties to the *Sandoz* litigation agreed would bind their litigation as well for purposes of the preliminary injunction motion, the Northern District of Illinois denied Abbott's motion for a preliminary injunction, finding that Abbott was unlikely to prevail on the merits at trial.

This court detects no abuse of discretion in the Northern District of Illinois' preliminary injunction denial. As described above, the '507 patent is properly construed to exclude Crystal B, both as to literal and equivalent infringement. Thus, this court need not delve into the Northern District of Illinois' clarifications of the Eastern District of Virginia's claim constructions. The Northern District of Illinois succinctly concluded: "[w]e know that Crystal B was known to the plaintiffs because it had been included in the Japanese '199 patent. Thus we conclude that the plaintiffs deliberately excluded from the definition of Crystal A, cefdinir monohydrate, which is Crystal B." *Id.* at 775.

As to the alleged presence of small amounts of Crystal A in Sandoz and Teva's products, Abbott's evidence did not persuade the Northern District of Illinois. *Id.* This court perceives that decision as well within the trial court's discretion. As additional support, the Northern District observed that there was no evidence that any trace amounts of cefdinir anhydrate, i.e. Crystal A, in Sandoz and Teva's products "could be a contributing factor in the efficacy" and that even "if there is a small amount of cefdinir anhydrate in defendants' products, we do not conclude that this could cause literal infringement." *Id.* While these may be misstatements of the law, be-

cause *de minimis* infringement can still be infringement, *see* 35 U.S.C. § 271(a); *see also SunTiger, Inc. v. Sci. Res. Funding Group*, 189 F.3d 1327, 1336 (Fed. Cir. 1999) ("If a claim reads merely on a part of an accused device, that is enough for infringement."), this court need not reach that issue in a preliminary injunction context which affords the trial court broad leeway to discern a "likelihood of success." Likewise the district court may have overstated the relevance of efficacy, because the '507 patent contains no claim limitations relating to efficacy. But these misstatements were harmless because they merely formed an alternative basis for the Northern District of Illinois' reasonable assessment of the evidence proffered by Abbott for its preliminary injunction motion. As noted, this court sustains the trial court's discretion based primarily on its administration of the proper claim construction and its finding that Abbott was not likely to show Sandoz and Teva's products contained any Crystal A at all.

CONCLUSION

The Eastern District of Virginia correctly construed the '507 patent's recitation of "crystalline" in each of the asserted claims as limited to Crystal A, as outlined in the specification. Because Abbott scrubbed all references to Crystal B in the '507 patent's specification, which were present in the '507 patent's parent foreign application, Abbott clearly demonstrated its intent to limit the '507 patent to Crystal A. This intent was further underscored by comments made during prosecution. As such, Abbott is unable to recapture Crystal B through broad claim language or under the doctrine of equivalents. The Eastern District of Virginia therefore properly con-

cluded on summary judgment that Lupin's cefdinir product did not infringe claims 1-5 literally or claims 2-5 by equivalency. Similarly, the Northern District of Illinois did not abuse its discretion in declining to enter a preliminary injunction against Sandoz and Teva's cefdinir products.

AFFIRMED

COSTS

Each party shall bear its own costs.

DISSENT BY: NEWMAN; MAYER; LOURIE

DISSENT

NEWMAN, *Circuit Judge*, with whom *Circuit Judges* MAYER and LOURIE join, dissenting from en banc Section III.A.2.

The court today acts *en banc* to overturn a century of precedent and practice, and holds that a new product that is difficult to describe without reference to how it was made, but that is nonetheless a new and unobvious product, cannot be protected as a product if its description is aided by reference to how it was made. Heretofore a new product whose structure was not fully known or not readily described could be patented as a product by including in the product description sufficient reference to how it can be made, to distinguish the new product from prior

art products. Patentability was determined as a product, independent of any process reference in the claim, and validity and infringement were based on the product itself. This expedient for patenting products whose structure was not fully known at the time of filing the patent application has been called the "rule of necessity." It was pragmatic, fair, and just, for it attuned patent law and practice to the realities of invention.

Today the court rejects this expedient and discards this practice, ruling that all claims containing a process term under the rule of necessity now must be construed, for purposes of infringement, as limited to use of any process term that was used to assist in defining the product. That is, such a product is not patented as a product, however it is produced, but is limited to the process by which it was obtained. This is a new restraint on patents for new products, particularly today's complex chemical and biological products whose structure may be difficult to analyze with precision. It is a change of law with unknown consequences for patent-based innovation.

The court acts *sua sponte*, without explanation of what policy is intended to be served by this change, without consideration of the technologies that may be adversely affected by elimination of this expedient, without notice to those whose property rights may be diminished. In so doing, the court departs from statute, precedent, and practice. This change is as unnecessary as it is flawed, gratuitously affecting inventions past, present, and future. I respectfully dissent.

DISCUSSION

For most product inventions, the process by which the product was made, whether or not the process is itself a patentable invention, is not stated in the product claims. However, as the variety and complexity of invention and technology have increased, various forms of product claims with process terms have been used in specific circumstances, depending on the nature of the invention.[1] The form here at issue relates to product claims for new and unobvious products whose structure is not fully known, and for which process parameters are used to aid in defining the product. This claiming expedient has been recognized since at least 1891.

The court today overturns this expedient for all circumstances, brooking no exception. Acting *en banc* for the purpose, the court rules that if any process term or descriptive aspect is included in a product claim to aid in distinguishing a new product, the claim cannot be infringed by the identical product unless the same process aspect is used in making the accused product. The court holds that it is irrelevant whether the product is new or was known, irrelevant whether the product could have been fully described by its structure at the time of the patent application, irrelevant whether the particular inven-

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[1] As discussed by Eric P. Mirabel, *Product-By-Process Claims: A Practical Perspective*, 68 J. Pat. & Trademark Off. Soc'y 3, 3-4 (1986), the various forms of product-by-process claims include "true" product-by-process claims, product claims with a process limitation, product claims with a process-derived structural element, and product claims with functional terms.

tion is a new product or is actually a process. The court adopts a simplistic universal rule, thereby targeting a small but significant class of inventions. The effect of this decision on innovation in complex fields of science and technology is unknown to the court, for we have had no advice on the consequences of this change of law. My dissent is directed as much to the court's procedure, as to the substance of the court's decision.

I. PROCEDURE

The court has given no notice of this impending *en banc* action, contrary to the Federal Rules of Appellate Procedure and contrary to the Federal Circuit's own operating procedures. The *en banc* court has received no briefing and held no argument, although the Federal Rules so require. The communities of inventors, innovators, and the public who may be affected by this change of law have had no opportunity to be heard. The court has received no information concerning the effect on patents that were granted based on this long-established practice, no advice on what kinds of inventions may now lie fallow because they are unprotected. Nor does the court explain its suspension of the standards of judicial process.

The Federal Rules have the force of law. 28 U.S.C. §2072. Federal Rules of Appellate Procedure 34 and 35 are here implicated. Rule 34 provides that "oral argument must be allowed in every case" unless certain specific exceptions exist:

> **Rule 34(a)(2) Standards**. Oral argument must be allowed in every case unless a

> panel of three judges who have examined the briefs and record unanimously agrees that oral argument is unnecessary for any of the following reasons:
>
> (A) the appeal is frivolous;
>
> (B) the dispositive issue or issues have been authoritatively decided; or
>
> (C) the facts and legal arguments are adequately presented in the briefs and record, and the decisional process would not be significantly aided by oral argument.

Applying the Rule 34 standards, it is clear that (A) this appeal is not frivolous and (B) the dispositive issue has not been authoritatively decided, for it is currently being addressed *en banc*. There has been (C) no briefing and no record to the court, and this is not a case in which the decisional process would not be aided by oral argument. The *en banc* court has heard no argument, and has received neither written nor oral exploration of the diverse aspects of this long-established claiming practice.

Federal Rule of Appellate Procedure 35 has also failed of compliance. That rule recognizes the exceptional nature of *en banc* hearing or rehearing, and identifies the two circumstances warranting such procedure:

> **Rule 35(a)** . . . An en banc hearing or rehearing is not favored and ordinarily will not be ordered unless:
>
> > (1) en banc consideration is necessary to secure or maintain uniformity of the court's decisions; or
> >
> > (2) the proceeding involves a question of exceptional importance.

When an *en banc* hearing or rehearing is ordered *sua sponte* by the court, whether for uniformity of decision or on a question of exceptional importance, the hearing or rehearing must receive the appellate process set by the Rules.

I agree that *en banc* review is appropriate, for this apparent conflict in our precedent has existed since 1992. Now that the court has undertaken to resolve the conflict, the withholding of public notice, or even notice to the parties to this case, is devoid of justification. The question is of importance, but there has been no assertion of urgency sufficient to require bypassing the standard appellate procedures. The breadth of the *en banc* court's ruling, the solidity of the precedent now overruled, the importance of the technologies affected, and the untold issued patents that are now placed in limbo, require this court's compliance with Federal Rules 34 and *35*.

The Federal Circuit has recognized that it can benefit from the advice of those knowledgeable in the

law and its purposes, in the areas of our nation-wide responsibility. Patent law has a direct impact on innovation, industry, and technological advance, and when an *en banc* ruling may change the law affecting some areas of technology and the industries based thereon, this court has routinely sought to be informed, by the parties and *amici curiae*, of relevant concerns. When the impact of a *sua sponte* change of law transcends the interests of the parties to the specific case, notice to the interested public, as well as to the parties, is fundamental to due and fair process. The Federal Circuit's Internal Operating Procedure (IOP) 14 was adopted to implement these principles:

> IOP 14.3(c) If the sua sponte petition for hearing en banc is granted, a committee of judges appointed by the chief judge, which shall normally include the judge who initiated the poll, shall within seven working days (fourteen working days between June 21 and September 11) transmit on a vote sheet to the judges who will sit en banc an order setting forth the questions proposed to be addressed by the court en banc. The clerk shall provide notice that a majority of the judges in regular service has acted under 28 U.S.C. §46 and Fed. R. App. P. 35(a) to order the appeal to be heard en banc, and indicate any questions the court may wish the parties and amici to address. Notice shall be given that the court en banc shall consist of all circuit judges in regular service who are not recused or disqualified. Addi-

tional briefing and oral argument will be ordered as appropriate.

United States Court of Appeals for the Federal Circuit, Internal Operating Procedures at 40, *available* at http://www.cafc.uscourts.gov/pdf/IOPs122006.pdf. This IOP has not been followed. No notice was given, even to the parties, that the court had ordered this question to be reheard *en banc*; nor did the court advise the parties or the public as to the aspects being addressed for *en banc* decision. The court is acting *sua sponte*, without notice and without argument and without an opportunity for participation. By bypassing this court's standard operating procedure, as well as violating the Federal Rules of Appellate Procedure, the court has deprived itself of input concerning the experience of precedent, of advice as to how this change of law may affect future innovation, and of guidance as to the effect on existing property rights.

II. PRECEDENT AND PRACTICE

The court's opinion does not mention the long-established precedent that it is overturning. This is not a simple conflict between isolated rulings of the Federal Circuit; it is a change of law and practice with roots in century-old decisions. I start with this precedent, for the expedient of what came to be called the "rule of necessity" originated in the recognition, by the courts and the Patent Office, that not all new products could be fully described by their structure, due to the state of scientific knowledge or available analytical techniques. It was also recognized, over a century ago, that sufficient distinction

from prior art products could sometimes be achieved by reference to how the product was made. Thus the courts and patent administrators established the exception that permitted inclusion in a product claim of sufficient recitation of how the product was made, to aid in identifying the product and distinguishing it from the prior art. This claim form was loosely called a "product-by-process" form, although that term includes a variety of situations, *see* n.1 *supra*, having diverse legal consequences. The only form here at issue is that in which the product is new and its structure is not fully or readily known, such that its definition as a product is aided by referring to how it was made. Since before 1891, this has been an accepted way to claim products as products, recognizing that this is an exception to the general rule that new products are claimed without reference to the process by which they are produced.

This exception was discussed in 1891 in *Ex parte Painter*, the Commissioner of Patents explaining that when there is entitlement to a patent on a new article of manufacture, it can be claimed by reference to the process of producing it, when the inventor lacks other language to "define and discriminate" the invention:

> It requires no argument to establish the proposition that *as a rule* a claim for an article of manufacture should not be defined by the process of producing that article. On the other hand, when a man has made an invention his right to a patent for it, or his right to a claim properly defining it, is not to be determined by the

> limitations of the English language. When the case arises that an article of manufacture is a new thing, a useful thing, and embodies invention, and that article cannot be properly defined and discriminated from prior art otherwise than by reference to the process of producing it, a case is presented which constitutes an exception to the rule.

1891 C.D. 200, 200-01 (Comm'r Pat. 1891). The Commissioner cited, as an earlier example of this exception, the claim in *Globe Nail Co. v. U.S. Horse Nail Co.*, 19 F. 819 (C.C.D. Mass. 1884) (sustaining validity of claim directed to horse-shoe nail claimed by reference to its process of manufacture, and finding it infringed by the accused nail having only a "trivial and unsubstantial variation" from the claimed product). In contrast, where the patent application made clear that the product could be described by its structure, the Patent Office ruled that the exception did not apply. *See, e.g., Ex parte Scheckner*, 1903 C.D. 315, 315-16 (Comm'r Pat. 1903) (sustaining rejection of claim directed to an etched printing-plate that "specifies certain steps by means of which the etching is accomplished" because other claims "define the plate in terms of its structure").

This expedient has been discussed in various judicial decisions. In all cases the issue has not been whether this expedient was available, for its availability was not challenged; the issue was simply its application to the particular facts. For example, at a time when it heard direct appeals from Patent Office

rulings, the D.C. Circuit remarked on this "only exception" to the general rule of product claiming, stating:

> It is a well-settled rule of patent law that claims for a product which is defined by the process of producing it will not be allowed; and the only exception to this rule seems to be in cases where the product involves invention and *cannot be defined except by the process used in its creation.* In extreme cases of this character, the product may be allowed; but that is not this case, especially in view of the broad claims allowed appellant in his copending application . . . .

In re Brown, 29 F.2d 873, 874, 1929 Dec. Comm'r Pat. 164 (D.C. Cir. 1928) (emphasis added).

The Court of Customs and Patent Appeals discussed precedent involving claims for processes and products in various factual situations, and summarized that:

> Where it is possible to define a product by its characteristics, the practice is clearly settled that this should be done. Where, however, the product is novel and involves invention and *cannot be defined except by the steps of the process involved in its creation*, there are cases holding that such a claim may be allowed, and it has been sustained by a Court.

In re Butler, 37 F.2d 623, 626, 17 C.C.P.A. 810, 1930 Dec. Comm'r Pat. 187 (CCPA 1930) (emphasis added) (quoting *Ex Parte Feisenmeier*, 1922 C.D. 18 (Comm'r Pat. 1922)). The CCPA then found this rule inapplicable to the facts of Butler's invention, explaining that "the record at bar does not meet this requirement [that the product was new]." *Id.*

In *In re Lifton,* 189 F.2d 261, 38 C.C.P.A. 1119, 1951 Dec. Comm'r Pat. 438 (CCPA 1951), the CCPA again commented on this exception for product claims, stating that when "proper article claims" were possible they must be used, with the exception of when such claims are "impossible":

> This court has uniformly held that a claim for an article must define the article by its structure and not by the process of making it. The one exception to this rule, where the invention is the article and *it is impossible to otherwise define it,* is clearly ruled out in the present case be cause appellant has demonstrated the possibility of proper article claims by including several devoid of process limitations.

Id. at 263 (emphasis added, citations omitted). The court again recognized "the one exception," holding once again that it does not apply when the product can be described independently of the process of making it.

These inquiries into the facts warranting application of the exception demonstrate that the rule of ne-

cessity was seldom applied, but was nonetheless recognized both by the courts and the Patent Office. Decisions of the Patent Office Board of Appeals illustrate the practice. *See, e.g., Ex parte Pfenning, 65 U.S.P.Q. 577 (Pat. Off. Bd. App. 1945)* (allowing claim "directed to a product which results from the method of claim 9" in light of applicant's argument that "it is impossible in the instant case to define the product adequately in terms of the elements which compose it or in terms of its physical characteristics"); *Ex parte Lessig, 57 U.S.P.Q. 129 (Pat. Off. Bd. App. 1943)* (allowing claim for a "product containing vulcanized rubber" strongly adhered to fibers which "has been prepared by the process of claim 4" because "it is not possible to otherwise distinguish over the art of record").

Commentators have explained that this claiming practice became of increasing importance as the complex sciences blossomed. *See, e.g.*, Mark D. Passler, *Product-by-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act, 49 U. Miami L. Rev.* 233, 233 n.3 (1994) ("Such claims are often used by companies to patent complex drug or chemical products whose structure is not completely understood and, therefore, can only be accurately described by the process through which it is made."). It is well known that the full structure of some chemical and biological products is not always known at the time the patent application is filed. Indeed, it is a tenet of the scientific method that explanation and theory tend to follow, not precede, the observation of a development in the science.

The CCPA continued to recognize the use of process terms to aid in describing new products--the form of claim sometimes called a "pure" product-by-process claim, *see* n.1 *supra*--and repeatedly ruled that such claims are properly viewed as product, not process, claims. The court also disallowed such claims where the product itself was not novel and unobvious. The court confirmed that such a claim, when justified for a novel and unobvious product, is properly construed as encompassing the full scope of a product claim. For example, in *In re Bridgeford*, 357 F.2d 679, 53 C.C.P.A. 1182 (CCPA 1966), the court again explained that a new product may be defined by the process of making it if there is no other way to describe the product, stressing that "the invention so defined is a product and not a process," *id.* at 682. The *Bridgeford* court relied on this view of the scope of the product-by-process claims in a related patent, and held unpatentable for double patenting claims that defined the "product per se." *Id.* at 680. The court explained that product-by-process claims are true product claims, and overruled the suggestion in *In re Freeman*, 166 F.2d 178, 181, 35 C.C.P.A. 920, 1948 Dec. Comm'r Pat. 276 (CCPA 1948), that product-by-process claims are "dependen[t] . . . on process limitations" and therefore coextensive with process claims. *Bridgeford*, 357 F.2d at 683 n.6 ("While there is some language in *Freeman* to support the contention that a product-by-process type claim differs only 'in scope' from a process type claim and they therefore 'are directed to a single invention,' (166 F.2d at 181) so far as this is inconsistent with our holding here it must be overruled.").

My colleagues misstate the holding of *Bridgeford*, for *Bridgeford* directly contravenes today's holding. In *Bridgeford* the CCPA noted that "some courts" have construed claims with process steps as limited to the recited process, *id.* at 683 n.5, apparently without inquiring whether the rule of necessity justified full product scope for the invention at issue. The CCPA's observation that patents are construed inconsistently in other courts cannot be taken, as apparently do my colleagues, as error by the CCPA. To the contrary, the inconsistency among courts led eventually to consolidation.[2]

Again in *In re Brown*, 459 F.2d 531, 59 C.C.P.A. 1036 (CCPA 1972), the CCPA explained that product-by-process claims are product claims, not process claims, and that the patentability of the product must be established independently of the process by which it is identified. *See id.* at 535 ("[I]n spite of the fact that the claim may recite only process limitations, it is the patentability of the *product* claimed and *not* of the recited process steps which must be established.").

Other decisions discussing application of this expedient to claims directed to complex new products include *In re Pilkington*, 411 F.2d 1345, 1349, 56 C.C.P.A. 1237 (CCPA 1969) ("While we are satisfied

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[2] The Hruska Commission Report, which informed the debate that eventually led to the formation of our court, described the varying attitudes towards patents held by the regional courts of appeal and the variations in patent rulings among the circuits. *See Commission on Revision of the Federal Court Appellate System Structure and Internal Procedures: Recommendations for Change*, 67 F.R.D. 195, 370 (1975).

that the references of record do not anticipate appellant's glass or demonstrate that it would be obvious, the differences between that glass and the glass of the prior art do not appear to us to be particularly susceptible to definition by the conventional recitation of properties or structure."), and *In re Fessmann*, 489 F.2d 742, 743 (CCPA 1974) (affirming obviousness rejection of product-by-process claim directed to a "liquid smoke" product, but observing that prior art compositions "are complex mixtures of the chemical compounds which can be derived from wood" which "defy simple characterization and this fact presumably accounts for the use of product-by-process claims"). The need for this expedient, and the proper scope afforded such claims, is summarized in the treatise *Walker on Patents*:

> [P]atent rights over a chemical product are typically independent of the process by which the product is made, and are particularly valuable because of this fact. This independence is normally accomplished by defining the product in terms of its structural features alone, with no reference in the claims to process steps whatsoever. *The state of chemical technology, however, is sometimes too limited for a structural description of this type to be made.* The structure of some chemicals, especially those including elaborate polymer chains, cannot be accurately determined. The same chemicals, however, may be both economically valuable and technologically reproducible, in the sense that they can be reliably made by subject-

> ing a particular set of raw materials to a particular set of process steps.
>
> * * *
>
> The law reacted to these difficulties by making it easier to obtain traditional product protection over this special class of chemicals. The inventor was allowed to describe such a chemical in terms of how one gained possession of it, that is, by way of the process steps by which it was made. Once he did so, the law preserved to the inventor the fullest measure of product-only protection that it could; *it treated the process recitations as proxies for the direct recitations of structure that could not be made.* Such a claim was therefore equivalent to one stated in terms of structure only. It would broadly dominate all methods by which the chemical could be made or used. At the same time, it carried the same dangers of running afoul of the art: it would be anticipated if the chemical had been produced previously, even if by a method other than what the inventor disclosed.

1 *Moy's Walker on Patents* §4:74 (4th ed. 2008) (emphases added).

The *en banc* court appears to misunderstand this precedent, for my colleagues now state that "binding case law" of the Court of Customs and Patent Appeals and the Court of Claims mandates a single rule for all claims that contain any process terms,

whether the product is novel or known, citing *In re Hughes*, 496 F.2d 1216 (CCPA 1974), for this proposition. However, *Hughes* does not state this proposition; *Hughes* stands for the contrary proposition. In *Hughes* the question was the patentability of claims directed to "shakes" as are used in roofing, as follows:

> 12. Shakes manufactured from a shake bolt by the process of making a plurality of cuts into and across the shake bolt to an extent to establish predetermined tip lengths, and splitting the weather end portions of the shakes from the bolt by starting the splits at the inner ends of the cuts and continuing the splits to the end of the bolt.

This claim had been rejected as an improper product-by-process claim, on the ground that the product could be described without including process steps. The *Hughes* court acknowledged the general rule against product-by-process claiming, but also explained the "proper exception to the general rule" as first set forth in *Painter*, as follows:

> [T]he Commissioner of Patents enunciated the general rule that a product should not be defined in terms of the process of making it. In *Painter*, a proper exception to the general rule was found on the ground that the product could not be properly defined and discriminated from the prior art otherwise than by reference to the process of producing it. This basic

> rule and the exception have been recognized and followed continuously by the Patent Office and the Courts.

Hughes, 496 F.2d at 1218 (quoting approvingly the Solicitor's argument). The court reaffirmed that "in spite of the fact that a product-by-process claim may recite only process limitations, 'it is the product which is covered by the claim and not the recited process steps.'" *Id.* Contrary to my colleagues' statement, *Hughes* did not eliminate this form of claim, or change its role as a product claim. Indeed, the *Hughes* court applied the exception and reversed the Board's rejection of a product-by-process claim, stating:

> We agree with appellant that the [general] rule should not be applied to the situation before us. We have been shown no true product claim which describes appellant's invention, in the words of the solicitor, "in terms of structure or physical characteristics." When an applicant seeks to describe his invention by a product-by-process claim because he finds that his invention is incapable of description solely by structure or physical characteristics, it is incumbent upon the Patent Office to indicate where, or how, the applicant's invention is, or may be, so described.

Id. at 1219. My colleagues could hardly have selected less apt support for their construction of product-by-process claims, for *Hughes* explicitly states that such claims are for the product, not the process.

In addition to misstating precedent of the CCPA, the *en banc* court also mischaracterizes the decisions of our predecessor the Court of Claims, stating that the Court of Claims' decisions support today's ruling. The court cites *Tri-Wall Containers v. United States,* 408 F.2d 748, 187 Ct. Cl. 326 (Ct. Cl. 1969), for this purpose. That citation, too, is mysterious, for in *Tri-Wall Containers* the court found that the claimed product was not "new" because it had been on sale for more than the permitted period, although the product that was on sale had been made by a different process than the process stated in the claim. The Court of Claims stated that the evidence showed that "the prior art product and the claimed product are structurally identical," *id.* at 751, and explained that a known product cannot be patented by including process terms in the claim:

> It is well established that a product claimed as made by a new process is not patentable unless the product itself is new. *The Wood-Paper Patent,* 90 U.S. (23 Wall.) 566, 596, 23 L. Ed. 31 (1874), *Cochrane v. Badische Anilin & Soda Fabrik ["BASF"],* 111 U.S. 293, 311, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1984). . . .
>
> . . . .
>
> More recent cases point out that the addition of a method step in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product. *Jungersen v. Baden,* 69 F. Supp. 922, 928

(D.C.S.D.N.Y. 1947), aff'd, 166 F.2d 807 (2d Cir. 1948), aff'd, 335 U.S. 560, 69 S. Ct. 269, 93 L. Ed. 235 (1949); *In re Stephens,* 345 F.2d 1020, 1023, 52 CCPA 1409, 1965 Dec. Comm'r Pat. 707 (1965).

Tri-Wall Containers, 408 F.2d at 750-51. This case applied the standard rule that old products cannot be patented--it contains no statement limiting the scope of claims that include process aspects to aid in describing new products. The Supreme Court cases cited in *Tri-Wall* are all directed to new processes for making old products--these are the same cases that the *en banc* court today incorrectly applies to new products, as I discuss *post.*

Contrary to my colleagues' statement, CCPA and Court of Claims precedent do not support today's *en banc* thesis. Our predecessor courts understood the complexity of patenting, and the CCPA consistently implemented the expedient whereby process terms contributed to the description of complex new products of incompletely known structure. These courts recognized the independence of product claims for new products, and did not limit such claims to the specific process steps that were used to aid in describing the product.[3]

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[3] The en banc court impugns the CCPA's experience. Maj. op. at 18 (stating that the CCPA had "virtually no jurisdiction to address infringement litigation"). The CCPA for many years addressed infringement litigation, in appeals from the International Trade Commission and its predecessor tribunals. *E.g., Sealed Air Corp. v. Int'l Trade Comm'n,* 645 F.2d 976, 68 C.C.P.A. 93 (CCPA 1981) (issues of validity and infringement); *Hale Fire Pump Co. v. Tokai, Ltd.,* 614 F.2d 1278, 67 C.C.P.A.

With the advent of the Federal Circuit, this court continued to apply these principles. In *In re Thorpe*, 777 F.2d 695 (Fed. Cir. 1985), the court explained that product-by-process claims are anticipated when the product existed in the prior art, even if the product was made by a different process. My colleagues are mistaken in stating that *Thorpe* held that all such claims are to be construed as process claims, even when the product is new and the rule of necessity justifies this mode of describing the invention. In *Thorpe* the product was not new; it was a known color developer for carbonless paper copy systems, and this court held that the PTO correctly rejected the claim to "the product of the process of claim 1," explaining that since the product was old it could not be claimed as a product, whether or not process steps are recited in the claim.

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121 (CCPA 1980) (issues of validity, scope, and infringement); *In re Orion*, 71 F.2d 458, 22 C.C.P.A. 149, Treas. Dec. 47123, T.D. 47123 (CCPA 1934) (issues of jurisdiction and infringement).

Our predecessor's legal and scholarly distinction in the field of patent law, and the high regard in which Congress and the innovation communities held the jurisprudence of the CCPA were a critical foundation for formation of the Federal Circuit and its charge to reinvigorate the role of the patent system in service to the nation's technological innovation. *See* 125 Cong. Rec. 23,462 (1979) (statement of Sen. DeConcini) ("It is a reflection of high esteem which Congress has for the sitting judges of the Court of Claims and Court of Customs and Patent Appeals that these judges will become the first judges of the new Court of the Federal Circuit.").

The facts of *Thorpe* did not concern the exception and expedient where process terms are invoked to describe a new product of complex structure. This exception is rarely invoked. The general rule requiring claims to have a process-free definition of the structure of a new product accommodates most inventions. Some recent exceptions are seen in emerging aspects of biotechnology. For example, in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 706 F. Supp. 94 (D. Mass. 1989), aff'd in relevant part, 927 F.2d 1200 (Fed. Cir. 1991), the district court considered the following claim:

> 4. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim 1, 2 or 3 in a manner allowing the host cell to express erythropoietin.

Id. at 108. The district court found claim 4 "ambiguous," explaining that while it is directed to a new product--this host cell--the words "transformed or transfected" appear to invoke a process. The district court recognized that "[i]n the traditional patent framework, a product is wholly separate and distinct from a process." *Id.* at 107. The court observed that "[a] product patent gives the patentee the right to restrict the use and sale of the product regardless of how and by whom it was manufactured," while "[a] process patentee's power extends only to those products made by the patented process." *Id.* (quoting *United States v. Studiengesellschaft Kohle*, 670 F.2d 1122, 1127-28, 216 U.S. App. D.C. 303 (D.C. Cir. 1981)). The district court, affirmed by the Federal Circuit, found this claim to be

valid and infringed as a product claim, and although many issues and arguments were present in this litigation, the applicability of the venerable rule of necessity was not at issue.

In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), the Federal Circuit addressed the interpretation and scope of claims exemplified by claim 13:

> 13. Highly purified and concentrated VIII:C prepared in accordance with the method of claim 1.

Claim 1 set forth the method referred to in claim 13, as follows:

> 1. An improved method of preparing Factor VIII procoagulant activity protein [VIII:C] comprising the steps of
>
> (a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,
>
> (b) eluting the VIII:C,
>
> (c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,
>
> (d) eluting the adsorbed VIII:C, and
>
> (e) recovering highly purified and concentrated VIII:C.

It was not disputed that the product was a new product, that the "highly purified and concentrated" blood clotting Factor VIII:C had not previously been obtained, and that a complete structural identification of Factor VIII:C was not available. The defendant Genentech had made its commercial Factor VIII:C not by the method set forth in claim 1, but by using a sample of the Scripps product to "clone" Factor VIII:C protein using recombinant DNA techniques. One question presented in the case was whether claims such as claim 13 were infringed by the same product produced by a different method, or whether such claims were infringed only if the accused infringer used the process of claim 1.

Scripps stressed that its product was novel and enabled and was patentable as a product, although the full structure of Factor VIII:C was not available at that stage of the science. The court addressed whether claims exemplified by claim 13, properly construed, were product claims, or whether they were limited to the specific processes in the process claims to which they referred. This court held that the claims were product claims. The court held that since claims are construed the same way for infringement as for validity, the question was whether the Genentech product was the same as the claimed product, not whether they were produced by the same process. The court remanded to the district court for this factual determination. *Scripps*, 927 F.2d at 1584.

After *Scripps* was decided, a panel of this court decided an appeal concerning plastic innersoles for shoes. In *Atlantic Thermoplastics Co. v. Faytex*

Corp., 970 F.2d 834 (Fed. Cir. 1992), the claims at issue were represented by:

Claim 24. The product produced by the method of claim 1.

In turn, claim 1 was as follows:

> 1. In a method of manufacturing a shock-absorbing, molded innersole for insertion in footwear, which method comprises:
>
> (a) introducing an expandable, polyurethane into a mold; and
>
> (b) recovering from the mold an innersole which comprises a contoured heel and arch section composed of a substantially open-celled polyurethane foam material, the improvement which comprises:
>
> (i) placing an elastomeric insert material into the mold, the insert material having greater shock-absorbing properties and being less resilient than the molded, open-celled polyurethane foam material, and the insert material having sufficient surface tack to remain in the placed position in the mold on the introduction of the expandable polyurethane material so as to permit the expandable polyurethane material to expand about the insert material without displacement of the insert material; and
>
> (ii) recovering a molded innersole with the insert material having a tacky surface

> forming a part of the exposed bottom surface of the recovered innersole.

The panel held that a claim in the form of claim 24 always requires use of the referenced method, and that it is irrelevant whether the product was new or known. The court stated that the rule of necessity, as applied in *Scripps*, is contrary to Supreme Court rulings. The panel stated that the decision in *Scripps* is incorrect. A majority of the Federal Circuit declined to resolve the conflict *en banc*, resulting in several further opinions. *E.g., Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279 (Fed. Cir. 1992) (dissents of Chief Judge Nies and Judges Rich, Newman, and Lourie from denial of rehearing *en banc*). Judge Rich wrote:

> [T]his whole excursion was unnecessary because the patentee admitted that claim 24, the product-by-process claim, was limited to the process. The claim read: "The molded innersole produced by the method of claim 1." There was, therefore, no occasion to review the law to determine how the claim should be construed. . . . We are not here to provide restatements of the law. Such restatements should not be made without an opportunity for all affected parties to be heard from. The affected parties here are not the vendors of inner soles but largely the entire chemical industry, particularly the pharmaceutical manufacturers.

Id. at 1280 (Rich, J., dissenting from denial of rehearing *en banc*).

Most trial courts continued to recognize the rule of necessity. For example, in *Trustees of Columbia University v. Roche Diagnostics GmbH,* 126 F. Supp. 2d 16 (D. Mass. 2000), the district court considered claims such as the following.

> 72. A eukaryotic cell into which foreign DNA I has been inserted in accordance with the process of claim 54.

The court referred to the *Scripps/Atlantic* conflict, concluded that the earlier panel decision controlled under the Federal Circuit's rule, *see Newell Companies, Inc. v. Kenney Manufacturing Co.,* 864 F.2d 757, 765 (Fed. Cir. 1988) ("This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *in banc*."), and applied the *Scripps* ruling, holding that the new cell was not limited by the process by which it was made.

The PTO also continued to apply the rule of necessity. In instructing examiners that products should whenever possible be described without reference to how they were made, the PTO continued to point out the exception that patentability as a product is not foreclosed when independent description is not available. The Manual of Patent Examining Procedure (MPEP) instructs the examiner to consider the structure implied by any process steps in the claim:

> The structure implied by the process steps should be considered when assessing the patentability of product by process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.

MPEP §2113 (8th ed., July 2008 rev.). This has been the practice since at least *Ex parte Painter* in 1891. I am surprised at the *en banc* court's casual misstatement about "the treatment of product-by-process claims throughout the years by the PTO," maj. op. at 17, for the statement is directly contrary to the treatment of such claims throughout the years by the PTO.

The *en banc* court's insistence that one universal rule should now be applied is contrary to the entire body of decisional law, including the Supreme Court cases cited by my colleagues. As I next discuss, in most of the cited cases the product was not a new product and thus was not patentable as a product, whether or not any process term was included in the claim. The Court consistently held that when the product was old and only the process was a patentable invention, a claim for the "product of that process" could not cover the old product made by a different process. That is, and has always been, the law. I comment briefly on the Court's cases that my colleagues misinterpret and misapply:

Cochrane v. BASF

The *en banc* opinion relies primarily on *Cochrane v. Badische Anilin & Soda Fabrik,* 111 U.S. 293, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1884) ("BASF"), even though my colleagues acknowledge that the product in that case was the well-known dye alizarine. The patent before the Court was a reissue patent that claimed artificial alizarine in the following way:

> Artificial alizarine, produced by either of the methods herein described, or by any other method which will produce a like result.

The Court held that since alizarine was a known product, the claim was limited to the patentee's two processes, stating:

> It was an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction from being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared, artificially, for the first time, from anthracite, if it was set forth as alizarine, a well-known substance. *Wood Paper Patent, 23 Wall. 566, 593 [(1874)]*. There was therefore no foundation for *reissue No. 4,321*, for the product,

> because, on the description given, no patent for the product could have been taken out originally.

111 U.S. at 311-12. The Court accordingly limited the claim to the two processes described in the patent, and in the portion of *BASF* quoted by my colleagues, the Court discussed the proofs needed to show infringement:

> [U]nless it is shown that the process of [the specification] was followed to produce the defendants' article, or unless it is shown that the article could not be produced by any other process, the defendants' article cannot be identified as the product of the process of [the specification]. Nothing of the kind is shown.

Id. at 310. The Court did not state, or imply, despite my colleagues' contrary theory, that a claim to a new and complex product that is of necessity defined and distinguished by the process by which it was made, can never be infringed unless that specific process is practiced. There was no issue in *BASF* of a product that could not be defined without reference to how it was made. The *BASF* Court, providing guidance, remarked on the importance of independent description of a patented product, in the following sentence cited by my colleagues:

> Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing

> can be held to infringe the patent which is not made by that process.

Id. at 310. This statement is indeed the general rule, as stated by the Patent Commissioner several years later in *Ex parte Painter*. However, *BASF* did not present the situation for which the expedient of necessity was created, for as the Court stated, the invention was "a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent, and is the process of preparing the known product alizarine from anthracine." *Id.* at 308-09.

This was not an instance of a new product describable only in terms of its process of manufacture. The *BASF* decision lends no support to today's *en banc* rule that every product claim that mentions a process step is always restricted to that process, with no exception, no expedient, no preservation of the distinctions among forms of claim based on the nature of the invention.

The Goodyear Dental cases

The *en banc* court also states that its new ruling is supported by two cases relating to a patent on the use of vulcanized rubber to form a plate for holding dentures, *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. (3 Otto) 486, 23 L. Ed. 952, 1877 Dec. Comm'r Pat. 171 (1876), and *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. (12 Otto) 222, 26 L. Ed. 149, 1881 Dec. Comm'r Pat. 131 (1880). Review of these

cases reveals no support for the *en banc* court's statement of their holdings. The claim at issue was:

> The plate of hard rubber or vulcanite, or its equivalent, for holding artificial teeth, or teeth and gums, substantially as described.

Davis, 102 U.S. (12 Otto) at 223. The claim was written in the then-standard format of incorporating the description in the specification through the phrase "substantially as described." This was not a product-by-process or product-of-the-process claim at all, for the claim contains no process distinction or limitation, but simply refers to the description in the specification. Nonetheless, the *en banc* majority appears to state that these cases mean that the Supreme Court requires that all claims for products whose method of production is set forth in the specification--as is required by the description and enablement requirement--cannot be infringed unless that method is used.

That is not what the *Goodyear Dental* cases said. The Court referred to the position of Goodyear Dental Vulcanite that its patent covered all dental plates made of vulcanized rubber, and held, upon reviewing the specification and the prior art, that the process of manufacture was what distinguished this dental plate from the prior art dental plates, and concluded: "The invention, then, is a product or manufacture made in a defined manner. It is not a product alone, separated from the process by which it is created." *Smith*, 93 U.S. (3 Otto) at 493. Were the claim not limited to this process, the Court concluded that the

claim would not have been patentable. *See id.* at 492 (holding that if the patent were for a "mere substitution of vulcanite for other materials, which had previously been employed as a base for artificial sets of teeth" then it "constituted no invention"). Four years later, considering the same patent in *Davis*, the Court emphasized that the claim was limited to use of vulcanized rubber or its equivalent, and held that since the accused infringer made its dental plate with celluloid, there could not be infringement. *See* 102 U.S. (12 Otto) at 228-30.

The court today cites these cases as definitive of the interpretation of claims with process elements, although the only process referent is the phrase "substantially as described." This flawed reasoning was disposed of in 1890 in the classic *Robinson on Patents*, and until now has not reappeared:

> In stating Claims certain phrases are frequently employed to which a special importance seems to be attached by applicants. Among these are the phrase "substantially as described" and others of the same meaning. These phrases import the same thing when used in a Claim as when elsewhere employed. They are neither necessary nor technical. The reference they make to the Description is always implied, and relates only to the essential features of the invention as therein delineated. They add nothing, therefore, to the certainty of the Claim, nor do they detract from it unless the claimant carelessly inserts them as a substitute for a

> more clear and definite statement of his invention.

II W.C. Robinson, *Robinson on Patents* 517 (1890) (footnotes omitted).

Merrill v. Yeomans

My colleagues also rely on *Merrill v. Yeomans,* 94 U.S. (4 Otto) 568, 24 L. Ed. 235, 1877 Dec. Comm'r Pat. 279 (1877). Again, the relevance is remote. The *Merrill* Court explained that the issue was the "correct construction of plaintiff's patent," *id.* at 569, construing the following claim:

> [T]he above-described new manufacture of the deodorized heavy hydrocarbon oils, suitable for lubricating and other purposes, free from the characteristic odors of hydrocarbon oils, and having a slight smell like fatty oil, from hydrocarbon oils, by treating them substantially as hereinbefore described.

Id. at 570. The Court examined the specification to determine what was invented, and found that the invention was directed solely to a process, not to a product. The Court then concluded that the claim's usage "new manufacture" referred to the manufacturing process, and not to the product. The claim was thus a process claim, and no "product-by-process" issue was presented. The Court concluded that the defendant's oil, which was made by a different process, did not infringe.

The *Merrill* Court discussed its practice of looking to the patent application and interpreting the claim in light of what was "really invented":

> [W]here it appears that a valuable invention has really been made, this court, giving full effect to all that is found in the application on which the Patent Office acted, will uphold that which was really invented, and which comes within any fair interpretation of the patentee's assertion of claim.

Id. at 573. This approach is inimical to the *en banc* court's theory that it is irrelevant what the patentee describes as his invention, and that if a process step is mentioned in the claim or "substantially described" in the specification, the claim always requires performance of that step. Although the Court in *Merrill* was not confronted with a situation of indescribable product or necessity bred of complexity--indeed no product at all was claimed--neither did the Court hold that every product invention must be limited by the process that produced the product.

The Wood Paper Patent case

The list of Supreme Court cases relied on by my colleagues continues with *The Wood Paper Patent, 90 U.S. 566, 596, 23 L. Ed. 31 (1874)*, where claims with the standard "substantially as described" language were construed in two reissue patents relating to the pulping of wood to make paper. The Court explained that one reissue patent was for "a product or manufacture, and not for the process by which the product may be obtained," and the other "for a proc-

ess and not for its product." *Id.* at 593. The Court examined the prior art and concluded that the claim for the product could not be sustained, because the product produced by the inventor's new pulping process was not new:

> Paper-pulp obtained from various vegetable substances was in common use before the original patent was granted to Watt & Burgess, and whatever may be said of their process for obtaining it, the product was in no sense new. The reissued *patent, No. 1448*, is, therefore, void for want of novelty in the manufacture patented.

Id. at 596. The Court then discussed the reissue patent for the "process and not for its product," and held this reissue void because it claimed a different invention than in the original patent. The Court also discussed several other patents directed to boilers used to produce paper-pulp, and to a process for bleaching straw. Nothing in this case concerns the product-by-process issue on which the court is today acting.

I cannot discern why the *en banc* court relies on *The Wood Paper Patent* case as invalidating *Scripps*, and the court has not attempted to explain.

Plummer v. Sargent

The *en banc* court also relies on *Plummer v. Sargent*, 120 U.S. 442, 7 S. Ct. 640, 30 L. Ed. 737 (1887), which again provides no support for my colleagues' thesis. This case again illustrates the Court's practice of reviewing what the patentee stated he in-

vented as set forth in the specification in light of the prior art. The claim in *Plummer* was for a "new manufacture," "substantially as described":

> What I claim and desire to procure by letters patent is the new manufacture hereinabove described, consisting of iron ornamented in imitation of bronze by the application of oil and heat, substantially as described.

Id. at 445. The trial court had found non-infringement because the defendant had used a prior art process for bronzing iron. This prior process was work of F.W. Brocksieper, an employee of the defendant's predecessor company. The Supreme Court affirmed, stating that the claims were limited to the process described in the specification:

> It seems necessarily to follow from this view either that the Tucker patents are void by reason of anticipation practiced by Brocksieper, or that the patented process and product must be restricted to exactly what is described . . . .

Id. at 449. The Court thus limited the claims to the process described by the patentee, not because of any rule about limiting a product to how it was made in the specification, but to sustain validity of the patent in view of the Brocksieper prior art. The decision in *Plummer* is unrelated to any rule of claim construction based on whether process terms are included in the claim.

These nineteenth-century cases do not relate to the *en banc* court's new universal rule of claim construction, whereby all product claims having process terms are treated as process claims, whatever the nature of the product, whatever the need for process descriptors, or any other factor that precedent shows to be relevant to the exception that is here at issue as to the use of and construction of such claims. Nor do any more recent Court cases.

General Electric v. Wabash

My colleagues also cite *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 (1938), although the relevance of this case is, again, not apparent, for it involved no product-by-process claims, but rather claims that recite the properties of the product. A typical claim is claim 25, which describes an electric lamp filament composed of tungsten grains of a size and shape that prevents sagging of the filament:

> 25. A filament for electric incandescent lamps or other devices, composed substantially of tungsten and made up mainly of a number of comparatively large grains of such size and contour as to prevent substantial sagging and offsetting during a normal or commercially useful life for such a lamp or other device.

Id. at 368. The Court held this claim "invalid on its face" for failing to provide a "distinct and definite statement of what he claims to be new, and to be his invention." *Id.* at 369. The Court stated that the de-

scription of the grains as "of such size and contour as to prevent substantial sagging and offsetting" was "inadequate as a description of the structural characteristics of the grains." *Id.* at 370. The Court also criticized the use of functional language in the claim, stating that such terms were too indefinite to provide clear guidance. *Id.* at 371. There was no issue of whether process steps in the claims were regarded as limiting, for there were no process steps in the claims. Instead, the Court stated that even the implicit inclusion of process steps could not save the claim, because the description of the process in the specification was inadequate:

> Even assuming that definiteness may be imparted to the product claim by that part of the specification which purportedly details only a method of making the product, the description of the Pacz process is likewise silent as to the nature of the filament product.

Id. at 373. The Court held the patent invalid for lack of a "distinct and definite" description of the invention, for the court "doubted whether one who discovers or invents a product he knows to be new will ever find it impossible to describe some aspect of its novelty." *Id.* Whatever the inadequacies in the Pacz description of his invention, the Court's optimistic view of scientific capability cannot be deemed to have barred all recourse to the rule of necessity when it is warranted, or to have voided the ensuing seventy-one years of Patent Office and judicial recognition of this pragmatic expedient.

No Supreme Court case discussed the problems of complexity and structural analysis that warrant this expedient, or created a legal solution to these problems. It is inappropriate, unsupported by law or precedent, and contrary to the purposes of patent systems, for this court now to rule that such products cannot be patented as products.

Regional circuit decisions

My colleagues also rely on some decisions of the regional circuits preceding this court's formation, announcing that "our sister circuits also followed the general rule that the defining process terms limit product-by-process claims," and citing two cases, one decided in 1915 and one in 1977. These cases do not support the *en banc* court's opinion,[4] and raised no issue of an expedient based on necessity.

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[4] It is curious to observe this en banc court extolling decisions of the regional circuits as authoritative, while it disregards the decisions of our predecessor courts and of this court. This court was created to remove patent law questions from the regional circuit courts. *See* H.R. Rep. 96-1300, at 20 (1980) ("Directing patent appeals to the new court will have the beneficial effect of removing these unusually complex, technically difficult, and time-consuming cases from the dockets of the regional courts of appeals. . . . [T]he central purpose is to reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist in the administration of patent law."); *see also Federal Courts Improvement Act of 1979: Hearings Before the Subcomm. on Improvements in Judicial Machinery of the Comm. on the Judiciary, U.S. Senate*, 96th Cong. 197 (1979) (statement of Hon. Henry J. Friendly) ("What is needed is a group of judges, some but not all patent lawyers, with scientific training and interest, aided both by law clerks of similar bent and by a staff of experts in a variety of technologies, such as the Court of Customs and Patent Appeals has had for years and the courts of appeals in the very nature of things, cannot . . . "). To cite two regional circuit decisions, while jettisoning the precedents of the court

In *Hide-Ite Leather Co. v. Fiber Products Co.*, 226 F. 34 (1st Cir. 1915), the appeal was of two process claims for making leatherboard, and a product claim for leatherboard "made from pulp" and reciting the second step in the process claims plus the reference "substantially as described." The accused infringer did not use the same first step of the process. The court found that the invention was for a process, not a product, and therefore that the product claim was not infringed.

My colleagues also cite *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870, 876 (3d Cir. 1977), in which the court used the specification to resolve an ambiguity in the language of a product claim relating to "replica wooden beams" made of foamed urethane. The court reviewed whether ambiguous claim language required a closed or open mold, for this determined the question of anticipation based on a prior art reference that used an open mold. Thus the court stated that the manufacturing process described in the specification was "of paramount importance," and construed the claim in light of that process as requiring a closed mold, thus preserving the claim's validity as against the prior art that used and open mold. The sentence quoted by my colleagues out of its context, does not relate to the *en banc* court's new rule concerning process terms in product claims, and the *Paeco* case raised no question of whether the product was capable of description apart from the process.

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uniquely qualified to address patent questions and selected to supplant the regional circuits, is puzzling.

In addition to these two cases inaptly cited by the *en banc* court, other regional circuit decisions also contradict this court's new thesis. In *Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.*, 259 F. 258 (6th Cir. 1919), the court stated: "Certain it is, in view of the weight of authority and the latest decisions, that the inventor of a new and useful product or article of manufacture may have a patent which covers it and gives a monopoly upon it regardless of great variations in the method of making." *Id.* at 261.

In *Buono v. Yankee Maid Dress Corp.*, 77 F.2d 274 (2d Cir. 1935) (L. Hand, J.), the court held invalid a product claim for a kind of "blind stitch" used in sewing, because the invention lay only in the process of producing the stitch, which itself "was not new." *Id.* at 279. While the stitch had not been claimed as the product of a particular machine or process, the court remarked on the conceivability of patenting such a product "merely as the product of a machine or process, even though it were anticipated if made in other ways," *id.*, observing that such a claim might serve a useful purpose in protecting against products that were produced by the same machine or process abroad and then imported. Of such a claim, wherein the product itself was anticipated but the process was new, the court stated "it would in that case not be infringed by anything but the product of the . . . process." *Id.* This routine statement of established law does not mean that when the product is itself new and useful and unobvious, it cannot be claimed as a product but must be tied to the machine that made it.

Judge Hand emphasized that this example related only to situations where the product itself was not new. The opinion explained that to be claimed as a product, the product "must be new as such, that is, regardless of the process or machine which makes it; and it must stand upon its own invention, again independently of the machine or process which makes it." *Id.* This was also the CCPA's view of product claims, providing the precedent carried forward to, and binding upon the Federal Circuit.[5]

III. THE *EN BANC* RULING

Defying precedent, the *en banc* court adopts for all situations "the basic rule that the process terms limit product-by-process claims," maj. op. at 17, whether the product is novel or known, and whether or not the new product could not have been fully described by its structure alone. The court eliminates the long-accepted expedient for new products whose structure is not fully known. While the *Scripps* deci-

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[5] There has been extensive commentary on this class of claim. *See, e.g.*, Jon S. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. Pat. Off. Soc'y 528, 559 (1960) ("Except in the chemical arts, a claim to a product must be in terms of the product's objective physical and chemical characteristics; but where these are unknown or impossible to express, a claim may define a product in terms of the process by which it is made. This product-by-process exception is to be distinguished from the use of process terminology as descriptive of a state of being."); Brian S. Tomko, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-by-Process Patents*, 60 Brook. L. Rev. 1693, 1696 (1995) (the *Atlantic* decision "pared the scope of a product-by-process patent to that of a glorified process patent").

sion is the only decision that is mentioned as "expressly overruled," maj. op. at 17, *Scripps* is only one of many cases now discarded.

The *en banc* majority's response to the dissenters is to state that "the inventor is absolutely free to use process steps to define this product" if its "structure is either not fully known or too complex to analyze," maj. op. at 19, but to eliminate the premise that the inventor thereby obtains a product claim, not a process claim. According to the majority, a patentee can continue to obtain product claims using process descriptors, but such product claims are treated as process claims for infringement. The applicant would still have to demonstrate patentability of the new product as a product (independent of the process), while enforcement of the patent against an identical product would be limited to the infringer's use of the process steps used as a descriptor. For the first time, claims are construed differently for validity and for infringement.

It has been an inviolate rule that patent claims are construed the same way for validity and for infringement. *See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement."); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1363 (Fed. Cir. 1998) ("Claims must be interpreted the same way for determining infringement

as was done to sustain their validity."); *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."); *Beachcombers, International, Inc. v. WildeWood Creative Products, Inc.*, 31 F.3d 1154, 1163 (Fed. Cir. 1994) ("We have already interpreted the claims for purposes of assessing their validity. The same claim interpretation of course applies to the infringement analysis."); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("claims must be construed the same way for validity and for infringement"); *Smithkline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1988) ("The claims of the '970 patent measure the invention at issue; thus, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); *see also* 5A *Chisum on Patents §18.01* (2007) ("A fundamental tenet of patent law is that a claim must be interpreted consistently for purposes of infringement and validity."); *id.* §18.03[2][h] (collecting cases).

As interpreted for validity, the claims obtained under the expedient of necessity are product claims, and are subject to the requirements of novelty, unobviousness, and all other requirements for new products, independent of how the products can be made. My colleagues hold that these are product claims for validity, but process claims for infringement. Departure from the rule that forbids such deviation requires sound reason, and fuller exploration

than the cursory brush-off dispensed by my colleagues.

I do agree with my colleagues that their logic is "simple." Maj. op. at 19. However, today's inventions are not simple. The needs of inventions of the past and present, and more so the future, are not simple. The public interest in invention and development of today's complex sciences, is not simple. The *en banc* court's "simple" hypothetical about "compound X, obtained by process Y," is simply irrelevant to the issues we must resolve. Scientists know that it is often easier to show that two products are the same, than to decipher their chemical or biological structure; for example, in the case at bar, comparing the X-ray diffraction patterns and absorption spectra could show that the products are the same, although their exact crystal structure is undefined. However, my colleagues announce that the only way to establish whether the accused compound is the same as the patented compound is by inquiring whether they were prepared by the same method. Maj. op. at 19-20 ("[W]hat analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes?"). That question has many answers, now stated to be irrelevant.

While the section of this opinion decided by the *en banc* court is largely directed to its reversal of precedent, the implementation of its ruling remains with the original panel. The panel decision enlarges the *en banc* ruling, further binding this court. The claims at issue state processes by which the new crystal form is "obtainable," although the specifica-

tion states that other methods might be used. The panel rules that a claim "cannot capture a product obtained by or obtainable by processes other than those explicitly recited in the claims." maj. op. at 21, finding authority in *BASF*, which I have discussed *ante*. My colleagues thus continue to misapply the Court's ruling in *BASF*, where the Court stated repeatedly that the product in that case was a known product. *BASF*, 111 U.S. at 311 ("It was an old article."). In *BASF* the Court responded to the patentee's argument that it was entitled to cover all artificial alizarine made by any process, by observing that the patentee had not shown how the infringing and patented products "can be recognized," *id.* at 310, an aspect at the opposite pole from the case at bar, where the patentee provided elaborate details as to how the patented and accused crystal forms can be recognized.

The panel also states that "the applicant's statement in the file wrapper that 'the method of preparation . . . is not considered the heart of the present invention' should not be afforded undue gravitas." Maj. op. at 22. This too is an aberration of precedent, and is contrary to the many rulings of the Supreme Court and this court that afford due gravitas to the applicant's statement of what has been invented. *See, e.g., BASF*, 111 U.S. at 308 ("It is very plain that the specification of the original patent, No. 95,465, states the invention to be a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent . . . ."); *Plummer v. Sargent*, 120 U.S. at 443

(quoting specification of companion patent, where inventor stated "My invention consists in a process of covering iron with a very thin coating of oil, and then subjecting it to heat, the effect of which is to leave upon the iron a firm film, which is very durable, and gives the iron a highly ornamental appearance, like that of bronze"). The Federal Circuit's emphasis on the importance of the specification has been repeatedly stated. *E.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (*en banc*) ("[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." (internal quotation marks omitted)).

The *en banc* court appears to misjudge the implications of its ruling, for the court states that it is now making available to "others the right to freely practice process Z [a different process] that may produce a better product in a better way." Maj. op. at 20. If others can indeed make a better product, this expedient presents no impediment. That is not the issue of this case. The issue is the right to make the same product, by making a process change that does not change the product. By now assuring that right, the exclusionary value of the claim to a new product is lost.

The purpose of the rule of necessity is to allow inventors of complex new products to obtain the patent scope to which their invention is entitled--the scope of the novel product they invented, no more and no less. The majority's change of law simply imposes unfairness as well as legal error on patent-supported advances.

SUMMARY

Precedent establishes that the correct construction of claims that recite process steps depends, like all claim construction, on what has been invented. No single rule fits all inventions. The construer must view the claims in light of the description of the invention in the specification, the prior art, and the prosecution history. In the complex law and practice of patents and inventions, the special expedient here of concern arises when the precise structure of a new product is not known from the information available when the patent application was filed. The law has enabled and endorsed this expedient of describing a product in order to claim it as a product, whereby validity and infringement are determined as a product, independent of any process term that was used to aid in defining the product. This expedient does not enlarge patent scope; it simply permits patenting what has been invented. A narrow but clear body of law has evolved to accommodate this need of complex technologies. This entire body of law is today overturned, *sua sponte* and without a hearing, without any participation of those affected, without identification of the intended benefits. I respectfully dissent from the *en banc* court's rulings, as well as the procedure by which they were reached.

LOURIE, *Circuit Judge*, dissenting from en banc Section III. A. 2.

I respectfully dissent from the court's en banc holding in Section III. A. 2 that product-by-process claims always require use of the recited process in order to be infringed.

I agree that there is substantial Supreme Court precedent that holds that product-by-process claims require use of the recited process for there to be infringement. However, many of those cases applied overly broad language to fact situations involving old products or used vague language that makes it difficult to determine whether the products were old or new. Clearly, however, when a product is old, a product-by-process claim cannot be interpreted as a claim to the product made by any means. The product is old and unpatentable per se. *BASF* in fact involved an old product. *See Cochrane v. Badische Anilin & Soda Fabrik,* 111 U.S. 293, 311, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1884) ("It was an old article.").

There is arguably a different situation that should apply to chemical-biological products today than to mechanical products of more than a century ago. When a product is new and the inventor claims it by a process of preparation, I fail to see why the product-by-process claim should not be interpreted as a product claim that can be infringed even when the product is made by means other than that recited in the claim. Supreme Court precedent dealing with old products, while utilizing broad language, does not foreclose that possibility. The Court years ago did not have occasion to consider today's innovations or decide whether a distinction should be made between a new chemical-biological product and an old product made by a new process.

And there may be differing results depending upon the exact wording of a claim at issue. For example, a claim reading "when made by" might only be infringed when the recited process is used by the

accused, as it is situational. On the other hand, a claim reading "obtainable by" refers to capability, so it might not require use of the process to infringe. "Obtained by" is ambiguous. Bright lines have their uses, but judging should take account of differing circumstances. In addition, of course, in order to sustain any claim for infringement, a patent owner must prove that an accused product is the same as that covered by an asserted claim. If the reason a product was claimed by its process was that its structure was unknown, then, if, at the time infringement is asserted, there still is no means to ascertain structurally whether the accused product is the same as that claimed, the infringement claim fails. However, that should not mean that a new product claimed by a process of preparation cannot ever be infringed when made by another process.

It may be that with today's analytical techniques there is little need for product-by-process claims. After all, claim 1 of the Abbott patent is a claim to a compound, not only by name, but also by certain of its characteristics. A claim to a product defined by its characteristics or properties surely is a proper claim.

However, product-by-process issues still seem to come before us and I would make a distinction between old products and new products in interpreting product-by-process claims. Accordingly, I respectfully dissent from the court's en banc holding.

LUPIN LIMITED, Plaintiff, v. ABBOTT LABORATORIES, and ASTELLAS PHARMA, INC., Defendants.

ABBOTT LABORATORIES, and ASTELLAS PHARMA, INC.,
Counterclaim Plaintiffs,
v.
LUPIN LIMITED, AND LUPIN PHARMACEUTICALS, INC.,
Counterclaim Defendants.

Civil Action No. 3:06cv400

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA, RICHMOND DIVISION

491 F. Supp. 2d 563

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June 14, 2007, Filed

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JUDGES: Robert E. Payne, Senior United States District Judge.

OPINION BY: Robert E. Payne

OPINION

MEMORANDUM OPINION

This matter is before the Court on Plaintiff's Motion for Summary Judgment on Noninfringement and Invalidity for U.S. Patent No. 4,935,507 (Docket No. 208). For the reasons set forth below, the motion is granted in part and denied in part.

BACKGROUND

This action involves U.S. Patent No. 4,935,507 ("'507 patent"), which covers Crystal A, a particular form of the antibiotic cefdinir. (See Docket No. 188, Mem. Op. at 23.) Astellas Pharma, Inc. ("Astellas") obtained the '507 patent in 1990, five years after it had obtained U.S. Patent No. 4,559,334 ("'334 patent"), which also covered forms of cefdinir. The *'334 patent* expired on May 6, 2007, and the '507 patent is set to expire on December 4, 2011.[1]

Because the '334 patent expired on May 6, 2007, Astellas can no longer prevent competitors from producing forms of cefdinir not covered by the '507 patent, which is limited in scope to Crystal A. Abbott Laboratories ("Abbott") holds a license from Astellas to practice the '507 patent. Pursuant to that license, Abbott makes and markets Crystal A in a branded cefdinir product called Omnicef(R), which currently has annual sales exceeding $ 600 million. Seizing on the expiration of the '334 patent, Lupin Limited ("Lupin") is now marketing a generic form of cefdinir to compete with Omnicef(R), and seeks a declaration that its product "has not infringed, does not infringe, and will not infringe any valid and enforceable claim of" the '507 patent. (Compl. for Declaratory J. at 1.) Abbott and Astellas have each filed counterclaims

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[1] Astellas received a patent term extension (PTE) for the '507 patent on January 19, 2001. Without that PTE, the '507 patent would expire on August 8, 2008. Whether the '507 patent's PTE is enforceable is disputed by the parties, but the parties have agreed to dismiss this claim in a Stipulated Order of Dismissal dated June 6, 2007 (Docket No. 349).

against Lupin, alleging infringement of the '507 patent. (Dockets No. 18 and 21.)

Lupin seeks summary judgment on six independent grounds: (1) non-infringement of Claims 1-5 of the *'507 patent*, both literally and under the doctrine of equivalents; (2) invalidity of the '507 patent for obviousness; (3) invalidity of the 507 patent for anticipation; (4) invalidity of the '507 patent for improper inventorship; (5) invalidity of the '507 patent for lack of enablement; (6) the absence of legal or equitable remedy for trace infringement. (See Lupin Limited's Mem. of Law in Supp. of Mot. for Summ. J. of Noninfringement and Invalidity for U.S. Patent No. 4,935,507 and Supplemental Declaration of Amy D. Brody ("Lupin Mem.").) Abbott and Astellas oppose Lupin's motion, and contend that summary judgment is inappropriate on any of those bases. (See Abbott Laboratories' and Astellas Pharma, Inc.'s Mem. in Resp. to Lupin's Mot. for Summ. J. ("Abbott and Astellas Mem.").) Oral argument was heard on May 21, 2007 and, for the reasons that follow, the Court now grants Lupin's summary judgment motion with respect to the literal infringement of Claims 2-5 and the infringement of all claims under the doctrine of equivalents.

DISCUSSION

Summary judgment is appropriate in a patent case, as in other cases, when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Nike Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 646 (Fed. Cir. 1994). When analyzing a summary judgment motion, the facts must be con-

strued in the light most favorable to the non-movant, and all reasonable inferences must be drawn in the non-movant's favor. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986).

A. Infringement

A determination of infringement requires a two-step, claim-by-claim analysis. See *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). First, the court must properly construe the claim; second, "the claim as properly construed must be compared to the accused device or process." *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001). An infringement issue is properly decided upon summary judgment when no reasonable jury could find, by a preponderance of the evidence, that every limitation recited in the properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents. Id.

1. Literal Infringement of Claim 1

After oral argument, the Court concluded that there were genuinely disputed issues of material fact which precluded an award of summary judgment on the literal infringement of Claim 1. In a Stipulated Order of Dismissal dated June 6, 2007 (Docket No. 349), the parties have agreed to dismiss without prejudice any claims related to the literal infringement of Claim 1. Because that issue has been resolved thusly by the parties, it is not necessary to address it further.

2. Literal Infringement of Claims 2-5

Claims 2-5 are product-by-process claims. (See Docket No. 188, Mem. Op. at 39.) In an order dated May 10, 2007 (Docket No. 234), the Court informed the parties that the Federal Circuit's decision in *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992) would govern the literal infringement analysis of Claims 2-5. That order was necessary because the parties disagree about whether the product-by-process infringement analysis should be controlled by *Atlantic Thermoplastics or Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Scripps and *Atlantic Thermoplastics* announce conflicting rules respecting the proper analysis of product-by-process claims in an infringement action. In *Scripps*, a panel of the Federal Circuit determined that "the correct reading of the product-by-process claims is that they are not limited to product prepared by the process set forth in the claims." 927 F.2d at 1583. One year later, the decision in *Atlantic Thermoplastics* held that "process terms in product-by-process claims serve as limitations in determining infringement." 970 F.2d at 846-47. As district courts have long acknowledged, those two holdings are at odds with one another. See, e.g., *Trustees of Columbia Univ. v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16, 31 (D. Mass. 2000).

Scripps and *Atlantic Thermoplastics* are different in substance as well as in result. While *Scripps* enunciated its rule without legal citation or significant analysis, see 927 F.2d at 1583, the *Atlantic Thermoplastics* decision reached its contrary conclu-

sion only after thoroughly examining both the history of product-by-process claims and the relevant precedent from the Supreme Court of the United States and the Federal Circuit pertaining to the infringement of such claims, see id. at 838-47. Indeed, the *Scripps* analysis was so brief by comparison that the *Atlantic Thermoplastics* court determined that *Scripps* would have been decided differently had Supreme Court precedent and other relevant authority been considered. *See* 970 F.3d at 838 n.2.

Notwithstanding the analytical parsimony in *Scripps*, some district courts have decided to follow *Scripps* because it was issued first and has not been overruled en banc. See, e.g., *Trustees of Columbia Univ.*, 126 F. Supp. 2d at 32. On the other hand, other district courts have concluded that *Atlantic Thermoplastics* constitutes a proper statement of the law, and, therefore, should govern the analysis of product-by-process claims. See, e.g., *Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7, 8-10 (D. Mass. 1993). Abbott and Astellas urge the Court to adopt *Scripps*, which offers a broader reading of product-by-process claims, while Lupin urges application of *Atlantic Thermoplastics*.

Having considered the matter further, the Court concludes, as it did in its order of May 10, 2007, that *Atlantic Thermoplastics* must control the product-by-process analysis because it, not *Scripps*, reflects controlling Supreme Court precedent. At oral argument on the motion for summary judgment, Abbott and Astellas disputed the Federal Circuit's interpretation of Supreme Court precedent in *Atlantic Thermoplastics*. (See Summ. J. Hr'g Tr. 185-89.) Having considered that argument, the Court finds no

basis for concluding that the decision in Atlantics Thermoplastics either misconstrued or misapplied the controlling decisions of the Supreme Court. Moreover, a district court is not at liberty to ignore relevant and controlling Supreme Court precedent simply because it was not considered in an appellate decision addressed to the same subject as the Supreme Court's antecedent decisions. Thus, because *Atlantic Thermoplastics* reflects the relevant and controlling Supreme Court precedent, and *Scripps* does not, the process terms in Claims 2-5 must "serve as limitations in determining infringement." 970 F.2d at 846-47.

Under the rule set forth in *Atlantic Thermoplastics*, Lupin's product cannot literally infringe any of Claims 2-5 unless it is made using each of the process limitations set forth in one of those claims. Abbott and Astellas have presented no evidence that Lupin is practicing the process steps set forth in Claims 2-5. Indeed, Abbott and Astellas have conceded that literal infringement of Claims 2-5 cannot be established if the product-by-process analysis is performed pursuant to the rule in *Atlantic Thermoplastics*. Therefore, Lupin's motion for summary judgment is granted with respect to the literal infringement of those claims.

3. Doctrine of Equivalents

If Lupin's product does not literally infringe Claims 1-5, it may still infringe under the doctrine of equivalents if there is "equivalence between those elements of the accused product and the claimed limitations of the patent invention that are not literally infringed." *Zelinski v. Brunswick Corp.*, 185

F.3d 1311, 1316 (Fed. Cir. 1999). The test of equivalency is directed to the individual claim limitations, and not to the invention itself. As the Supreme Court explained in *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*: "Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." 520 U.S. 17, 29, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997).

An element in the accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to one of ordinary skill in the art. *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1331-32 (Fed. Cir. 2001). A difference may be "insubstantial" if the accused product's element "performs substantially the same function in substantially the same way to obtain the same result as the claim limitation." *Eagle Comtronics, Inc. v. Arrow Commun. Labs., Inc*, 305 F.3d 1303, 1315 (Fed. Cir. 2002) (citation and internal quotations omitted). Under no circumstances, however, is this element-focused equivalency inquiry "allowed such broad play as to effectively eliminate [any] element in its entirety." *Warner-Jenkinson*, 520 U.S. at 29.

Notwithstanding the foregoing well-established, element-focused dispositive principles, Abbott and Astellas contend that Lupin's product infringes Claims 1-5 "because Lupin's product performs substantially the same function, in substantially the same way, to produce substantially the same result as the claimed crystalline cefdinir." (Abbott and Astellas Mem. at 12 (emphasis added).) Abbott and

Astellas focus, in particular, on the "bioequivalence" and "stability and solubility" similarities between Lupin's product and Crystal A. (Id. at 12-13.) Even if Abbott and Astellas are correct about the functioning of Lupin's product, no reasonable jury could conclude, based on a product-focused analysis, that Lupin's product contains elements insubstantially different from each and every limitation in one of Claims 1-5 (which focus on peak positions and process steps, not stability, solubility, or other characteristics associated with Crystal A as a whole). See *Schoell v. Regal Marine Indus., Inc.*, 247 F.3d 1202, 1210 (Fed. Cir. 2001) (noting that similarities between products as a whole do not, by themselves, allow inferences respecting the equivalence of individual elements and claim limitations). To the extent that Abbott and Astellas rely on characteristics of Lupin's product unrelated to the individual limitations set forth in Claims 1-5, their doctrine of equivalents theory is without merit.

However, Abbott and Astellas make three arguments which, at least, loosely relate to the individual limitations contained in Claims 1-4.[2] First, Abbott and Astellas claim that "the peak positions in Lupin's products are at most insubstantially different from the positions of the peaks claimed in the patent." (Abbott and Astellas Mem. at 14.) They base

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[2] Abbott and Astellas make no element-focused contentions with respect to Claim 5. (See Abbott and Astellas Mem. at 14-15.) That being the case, summary judgment is appropriate for noninfringement of Claim 5 under the doctrine of equivalents notwithstanding the merits of any element-focused arguments made by Abbott and Astellas with respect to Claims 1-4.

that argument entirely on a single paragraph in Dr. Atwood's first expert report. (*See id.*) In paragraph 50 of that report, Dr. Atwood states the following:

> Even a crystal of cefdinir with 6.0 - 7.5% w/w water in the lattice would contain the peaks recited in claim 1 of the '507 patent, but they would at most be insubstantially shifted by virtue of the expansion of the crystal lattice along the c direction upon the insertion of additional water molecules. In every material respect, crystalline cefdinir monohydrate and crystalline cefdinir hydrate containing 6.0-7.5% w/w water are substantially the same as each other.

(First Expert Report of Jerry L. Atwood P 50.) Under the doctrine of equivalents, this paragraph alone is insufficient to allow a reasonable jury to conclude by a preponderance of the evidence that Lupin's product infringes Claim 1. First, Dr. Atwood makes no mention whatsoever of Lupin's particular product. Instead, he offers a theoretical discussion comparing abstract hydrated forms of crystalline cefdinir that might share characteristics with Lupin's product. Second, Dr. Atwood does not conduct an element-by-element analysis of Claim 1 as compared to Lupin's product. For example, he does not say which particular peak in Lupin's product corresponds with the peak that must exist at about 14.7 and why the difference between the two peak positions is "insub-

stantial" to a person of ordinary skill in the art.[3] Thus, while Dr. Atwood's statements relate to the individual limitations in Claim 1 (the existence and position of peaks), he nevertheless "has not opined in a sufficient manner regarding infringement under the doctrine of equivalents." *Microstrategy, Inc. v. Business Objects, S.A.*, 331 F. Supp. 2d 432, 445 (E.D. Va. 2004). Without more, Dr. Atwood's conclusory and abstract opinion is simply insufficient to support a finding of infringement under the doctrine of equivalents with respect to Claim 1. *See* Schoell, 247 F.3d at 1210 ("The doctrine of equivalents is not a talisman that entitles a patentee to a jury trial on the basis of suspicion; it is a limited remedy available in special circumstances, the evidence for which is the responsibility of the proponent.")

Second, Abbott and Astellas contend that, even if Lupin's product does not show "peaks" at about 14.7 or about 22.0, it does show "increases in intensity" at those angles. (Abbott and Astellas Mem. at 14.) Abbott and Astellas again invoke Dr. Atwood to argue that those increases in intensity are insubstantially different from peaks. (Id.) However, Dr. Atwood's third declaration, on which Abbott and Astellas rely for this argument, does not equate "peaks" with mere increases in intensity. (*See id.* Ex. 9 PP 9-11.) For example, paragraph 9 of Dr. Atwood's third declaration depicts features which he labels "peaks," but, while those "peaks" take slightly different

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[3] Moreover, Dr. Atwood's conclusory opinion does not enable the Court to determine whether his theory of equivalence would "entirely vitiate" a particular claim element or otherwise render the peak limitations in Claim 1 impermissibly meaningless. *Warner-Jenkinson*, 520 U.S. at 39 n.8.

forms, each increase in intensity labeled a "peak" has an apex surrounded by a lower intensity measurement on each side. (Id. P 9.) While paragraphs 10 and 11 of the declaration do discuss the possibility that peaks may overlap, or that a peak may protrude as a "shoulder" from another peak, nothing in paragraphs 10 and 11 indicates that a peak, of any shape or size, may be anything other than an apex immediately preceded by and immediately followed by a lower intensity measurement. (*See id.* PP 10-11.) Therefore, Dr. Atwood's third declaration does not support Abbott's and Astellas' contention that mere "increases in intensity" are insubstantially different from peaks.

Even if Dr. Atwood's third declaration did support that argument, Dr. Atwood does not point out, on an element-by-element basis, which "increases in intensity" in Lupin's product correspond to the peaks required by Claim 1.[4] The failure to offer proof on that subject is fatal at this stage.

Third, and finally, Abbott and Astellas argue that Lupin's product infringes Claims 2-4 by equivalents because the processes described by Claims 2-4 may result in both Lupin's product and the crystalline cefdinir covered by the '507 patent. (See Abbott and Astellas Mem. at 15.) Therefore, Abbott and Astellas argue, "any difference between the two crystal forms is insubstantial." (*Id.*) Again, however, this argument improperly focuses on completed products and

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[4] Nor do Abbott and Astellas explain why the claim limitations in Claim 1 would not be rendered totally and impermissibly meaningless if mere "increases in intensity" could serve as infringing equivalents.

not on *Lupin's process steps*, which are the elements at issue here. In order to demonstrate infringement by equivalents, Abbott and Astellas must offer proof to show why *Lupin's processes* feature a step that is insubstantially different from each process limitation set forth in one of Claims 2-4. Abbott and Astellas offer no such proof. They certainly do not explain why *Lupin's processes* are insubstantially different from each process step described in one of Claims 2-4 simply because the processes in Claims 2-4 might produce Lupin's product (among others). Because Abbott's and Astellas' equivalency analysis with respect to Claims 2-4 fails to address the pertinent process steps - Lupin's-summary judgment for Lupin is required.

In sum, Abbott and Astellas largely make irrelevant product-focused arguments under the doctrine of equivalents, and, where their arguments do properly focus on individual claim elements, they do not offer supporting evidence sufficient to defeat Lupin's motion for summary judgment. Accordingly, summary judgment for Lupin is required with respect to the infringement of Claims 1-5 under the doctrine of equivalents.

B. Validity and Availability of Legal Remedies

After oral argument on the motion for summary judgment, the Court concluded that the existence of genuinely disputed material facts precluded summary judgment on Lupin's contentions respecting invalidity and the availability of remedies. In the Stipulated Order of Dismissal dated June 6, 2007 (Docket No. 349), the parties agreed to dismiss without prejudice any claims related to invalidity. Be-

cause those issues have been resolved by the parties, it is not necessary to address them further. In addition, because the issues related to infringement have been dismissed or resolved in favor of Lupin, the Court need not consider the availability of legal remedies to Abbott and Astellas.

CONCLUSION

For the reasons set forth above, Lupin's motion for summary judgment is granted with respect to the literal infringement of Claims 2-5 and infringement of all claims under the doctrine of equivalents. Lupin's motion is otherwise denied.

The Clerk of the Court is directed to send a copy of this Memorandum Opinion to all counsel of record.

It is so ORDERED.

Robert E. Payne

Senior United States District Judge

Date: June 14, 2007

Richmond, Virginia

Supreme Court, U.S.
FILED
NOV 18 2009
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No. 09-335

IN THE

Supreme Court of the United States

ASTELLAS PHARMA, INC.,
Petitioner,

v.

LUPIN LIMITED and
LUPIN PHARMACEUTICALS, INC.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENTS' BRIEF IN OPPOSITION TO THE PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit correctly concluded that Lupin did not infringe Astellas' patent claims, when (1) the lower courts held, and Astellas does not dispute here, that by its terms, the patent did not encompass the product produced by Lupin, and (2) Astellas conceded that Lupin's products were never made using the process steps that the patent claims required?

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

The parties to this proceeding are: Petitioner/Appellant Astellas Pharma, Inc. and Respondents/Appellees Lupin Limited and Lupin Pharmaceuticals, Inc. Abbott Laboratories, an appellant below, to date has neither joined Astellas' petition nor filed its own petition.

The Federal Circuit's decision in 2007-1446 (this case) was a final decision disposing of all issues between the parties. On appeal, the Federal Circuit heard this case with 2007-1400, which involved the same patent and the same plaintiffs and was an appeal of a denial of a preliminary injunction to plaintiffs Astellas Pharma, Inc. and Abbott Laboratories against defendants Sandoz, Inc., Sandoz GMBH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical.

Respondent/Appellee Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Respondent/Appellee Lupin Limited. There is no public corporation that owns 10% or more of the stock of respondent Lupin Limited.

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IN THE

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On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENTS' BRIEF IN OPPOSITION TO THE PETITION FOR WRIT OF CERTIORARI

STATEMENT OF THE CASE

I. Introduction

Petitioner holds a patent for a crystalline form of the antibiotic cefdinir ("the '507 patent"). As relevant here, there are two forms of crystalline cefdinir, commonly known as "Crystal A" and "Crystal B." Petitioner's licensee, Abbott, markets Crystal A under the brand-name "Omnicef." Respondent's generic version is almost exclusively Crystal B. Pet. App. 32. The question in this case is whether respondent's use of Crystal B violates petitioner's patent.

The district court held, and the Federal Circuit affirmed without dissent, that the first claim of the patent—which described the claimed invention by chemical name and x-ray signature—covered only Crystal A. Petitioner nonetheless argued that its second through fifth claims, so-called "product-by-process" claims, were broader and encompassed both Crystal A and the Crystal B used in respondent's generic drug.

The Federal Circuit rejected this argument on two independent grounds. First, it affirmed the district court's conclusion—based on the "language of the claims themselves, the specification, and the prosecution history," Pet. App. 13—that all of the patent claims (including the product-by-process claims) claimed only Crystal A, and not Crystal B. *Id.* at 13-17, 31. That fact-bound determination presents no question of general legal significance, is not challenged (or even acknowledged) by petitioner, and wholly resolves the case.

Second, using this case to clarify the proper treatment of product-by-process claims, the court also held en banc that product-by-process claims are not infringed except by a product produced by the same process. *See* Pet. App. 22. Because there was no dispute that respondent produced Crystal B by a method materially different from that described in the product-by-process claims, the court held there could be no infringement even if those claims had purported to patent Crystal B. *Id.* at 17-26. Three judges dissented from one product-by-process aspect of the en banc ruling, but took no position on the ultimate disposition of the case. *Id.* at 37-88.

The petition seeks review of this second alternative holding. In addition to having no relevance to the

outcome of this case, the dispute between the majority and dissenting judges below centers not on the proper general rule for product-by-process claims, but rather on whether the courts should recognize what the dissenters described as a "rarely invoked exception" for products that cannot be described in non-process terms. Pet. App. 59. Petitioner does not claim that this "rarely invoked exception" applies here, and indeed it would not. Instead, petitioner asks this Court to grant certiorari to adopt a novel rule embraced by none of the judges of the Federal Circuit and inconsistent with more than a century of this Court's precedent. That request should be denied.

II. Factual and Procedural History

1. Petitioner originally patented cefdinir in 1985. *Lupin Ltd. v. Abbott Laboratories*, 484 F. Supp. 2d 448, 451 (E.D. Va. 2007) (discussing origins of U.S. Patent No. 4,559,334, the "'334 patent"). Two years later, it filed a patent application in Japan for cefdinir "Crystal A" and "Crystal B". *Id.* Petitioner then applied in the United States for the '507 patent at issue in this case.

While petitioner's Japanese application separately distinguished "Crystal A" and "Crystal B" as distinct compounds and inventions, the U.S. application used the term "Crystalline" to describe cefdinir. Pet. App. 6-8.[1] The first claim in the '507 patent is a traditional product claim, which further characterizes the product by reference to its unique x-ray fingerprint from a "powder X-ray diffraction" test. *Id.* at 6.

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[1] The chemical name of "7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cepham-4-carboxylic acid (syn isomer)" identifies cefdinir whether or not in crystalline form.

Claims 2-5 are petitioner's product-by-process claims. Like Claim 1, they claim as their invention "Crystalline [cefdinir]"; they differ by incorporating a description of, and requiring, a particular process for making crystals, which varies in each of the claims.[2]

2. When petitioner's original '334 patent expired, respondents planned to introduce a generic form of cefdinir, composed almost entirely of Crystal B, to compete with Omnicef, which is composed of Crystal A. *See Lupin*, 484 F. Supp. 2d at 451. Prior to introducing the drug to market, respondents filed an action in the Eastern District of Virginia seeking a declaration that their generic did not infringe petitioner's '507 patent. Pet. App. 4.

The district court found no infringement. It first determined that the cefdinir described in Claim 1 was Crystal A, and Crystal A alone. *Lupin*, 484 F. Supp. 2d at 458. Moreover, the court held that no reasonable jury could find that Crystal B was sufficiently identical to Crystal A as to constitute infringement under the doctrine of equivalents. Pet. App. 98. Petitioner challenges neither finding in this Court.[3]

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[2] The independent claims within claims 2-5 read:

> "2. Crystalline [cefdinir] which is obtainable by acidifying a solution containing [cefdinir] at room temperature or under warming.
>
> 5. Crystalline [cefdinir] which is obtainable by dissolving [cefdinir] in an alcohol, continuing to stir the solution under warming, then cooling the solution to room temperature and allowing the solution to stand."

Pet. App. 7.

[3] Petitioner originally claimed that respondents' generic literally infringed its patents because it contained material amounts

The district court further construed the product-by-process claims to refer to multiple processes for making the same crystal as in Claim 1—namely, Crystal A. *Lupin*, 484 F. Supp. 2d at 454-59; Pet. App. 13-17.

In particular, the court concluded that the word "crystalline," as used in each of the claims, was intended to refer to Crystal A, and not as petitioner claimed, generically to any crystal form of cefdinir. *Lupin*, 484 F. Supp. 2d at 454-59; Pet. App. 13-17. The specification, the court noted, expressly described the invention to be Crystal A. *Lupin*, 484 F. Supp. 2d at 456. Moreover, the process steps in Claims 2-5 corresponded with the steps set forth in the specification for creating Crystal A. *Id.* at 457. And when petitioner intended to claim both Crystals A and B in its Japanese application, it did so expressly, specifically identifying each form separately and by name. *Id.* at 458.

Even if claims 2-5 had not been expressly limited to the Crystal A form of cefdinir, the district court held that respondents' generic would not infringe the product-by-process claims (2-5) because admittedly it is made by a different process. Relying on the Federal Circuit's decision in *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), the court explained that the process steps in a product-by-process claim "serve as limitations in determining infringement." Pet. App. 96 (quoting *Atl. Thermoplastics*, 970 F.2d at 846-47). Because petitioner had presented "no evidence that Lupin is practicing the process steps set forth in Claims 2-5,"

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of Crystal A, but subsequently abandoned that theory in the district court. Pet. App. 93.

the court held, there could be no literal infringement of those claims. Pet. App. 96.[4]

3. The Federal Circuit affirmed. A three-judge panel initially heard the case and issued a decision that wholly disposed of petitioner's claims on appeal. In addition, the Circuit used the case to clarify the scope of product-by-process claims. That portion of the opinion—circulated among the full court and issued en banc—provided an alternative ground for rejecting petitioner's claims in this particular case.

a. The three-judge panel first affirmed the district court's conclusion that the term "crystalline," in both the product and product-by-process claims, refers solely to Crystal A. Pointing to the Japanese application, the court observed that "[petitioner] knew exactly how to describe and claim Crystal B compounds. Knowing of Crystal B, however, [petitioner] chose to claim only the A form in the '507 patent." Pet. App. 14. Moreover, the court noted that the process steps were described in the specification as the "Process for Preparing Crystal A" and that the Japanese application had "recited these steps to distinguish between preparations for Crystal A and Crystal B." *Id.* 15 (citation and quotation marks omitted). In addition, the court concluded, "the prosecution history of the '507 patent shows a clear and intentional disavowal of claim scope beyond Crystal A." *Id.* at 16.

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[4] The court further held there was no infringement of Claims 2-5 by equivalents, Pet. App. 96-102, a conclusion upheld on appeal and not challenged in this Court. Pet. App. 34 ("Because Crystal B is not an equivalent of Crystal A, the [district court] did not err in granting summary judgment of noninfringement . . . .").

That conclusion, the panel recognized, was outcome determinative. *See* Pet. App. 36-37 (explaining that the court "correctly construed the '507 patent's recitation of 'crystalline' in each of the asserted claims as limited to Crystal A," and "therefore properly concluded on summary judgment that [respondents'] cefdinir product did not infringe claims 1-5").

b. Although the panel's construction of the term "crystalline" was sufficient to resolve the case, the court affirmed on an alternate ground as well, going en banc to resolve an issue that had persisted for 17 years over the scope of product-by-process claims. *See* Pet. App. 18 (discussing *Atl. Thermoplastics* and *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991)). The full court concluded that, when an applicant chooses to describe its invention in process terms, those terms limit the scope of the patent, such that an identical product made through a different process will not infringe the product-by-process claims. Pet. App. 17-26.

The court explained that this "rule finds extensive support in Supreme Court opinions" stretching back more than 100 years. Pet. App. 18. As early as 1884, this Court had established the general rule that "[e]very patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process." *Cochrane v. BASF*, 111 U.S. 293, 310 (1884). The rule arises in part, the Federal Circuit explained, from the fundamental requirement that patent protection extend no further than what the inventor has "particularly point[ed] out and distinctly claim[ed]" in his patent as his invention. Pet. App. 26 (quoting 35 U.S.C. § 112). "If

the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed." *Id.* Moreover, even when limitations on technology or knowledge prevent an inventor from describing a new substance in terms other than the process by which it is created, the court explained, those same impediments prevent a court from knowing whether a similar-seeming product produced by other means is, in fact, the same product. *Id.* at 25-26.

c. Three judges dissented from the en banc portion of the opinion, which they viewed as stating too sweeping a rule.

The principal dissent by Judge Newman did not dispute that, historically, product-by-process claims generally either were not allowed or were limited by their process terms. *See, e.g.*, Pet. App. 67-68 (acknowledging "the general rule" that "nothing can be held to infringe" a product-by-process claim "which is not made by that process") (quoting *BASF*, 111 U.S. at 310); *id.* at 45 (recognizing that "*as a rule* a claim for an article of manufacture should not be defined by the process of producing that article") (quoting *Ex parte Painter*, 1891 C.D. 200, 200 (Comm'r Pat. 1981) (emphasis in original)); *id.* at 54 (acknowledging "general rule against product-by-process claiming"). Instead, the dissent insisted that the there has long been a "rarely invoked" exception, Pet. App. 59, recognized in the case law of the Federal Circuit and its predecessors, for cases in which "the product is new and its structure is not fully or readily known, such that its definition as a product is aided by referring to how it was made," *id.* at 45.

Although it argued that the cases of this Court cited by the majority were distinguishable, the dissent

did not claim that this Court had ever recognized a "rule of necessity" exception. Instead, Judge Newman simply argued that none of this Court's prior cases "discussed the problems of complexity and structural analysis that warrant this expedient, or created a legal solution to these problems." Pet. App. 77. Writing separately, Judge Lourie acknowledged that "there is substantial Supreme Court precedent that holds that product-by-process claims require use of the recited process for there to be infringement," but he faulted those decisions for using "overly broad" language in cases that may not have involved new patentable products. *Id.* at 87.

Their criticisms of this Court's decisions aside, the dissenters recognized that their disagreement with the majority might affect very few cases as a practical matter. Judge Newman conceded that the majority's rule "accommodates most inventions," but speculated that identifying products in non-process terms might prove difficult "in emerging aspects of biotechnology." Pet. App. 59. Judge Lourie's dissent, however, acknowledged that advances in *other* forms of technology, like the powder X-ray diffraction technique used by petitioner in this case, may mean that "there is little need for product-by-process claims." *Id.* at 88.

In any event, none of the dissenters claimed that the exception they advocated applied here, where petitioner admittedly was able to identify in non-process terms Crystal A in Claim 1 of the '507 patent, and Crystal B in its Japanese application. Pet. App. 8. Indeed, none took issue with the panel's ultimate disposition of this particular case, including its alternative holding that the term "crystalline" limited the patent to Crystal A separate and apart from any

effect of the process terms. *See id.* at 37 (Newman, J., "dissenting from en banc Section III.A.2" only); *id.* at 86 (Lourie, J., same).

REASONS FOR DENYING THE PETITION

Petitioner asks this Court to decide whether product-by-process claims are "infringed by an identical product made by a different process." Pet. i. That question does not arise in this case, because the district court found that respondents produce a different product (Crystal B) than the one petitioner patented (Crystal A). That conclusion was based on the language of the patent and its prosecution history; did not depend on the legal limits of product-by-process claims; and is not challenged by petitioner in this Court. As a result, reversing the separate product-by-process holding would have no effect on the outcome of this litigation.

Moreover, even if the question raised by the petition were presented in this case, it would not be worthy of this Court's review. All of the judges below agreed that, as a general rule, product-by-process claims are limited by their process terms. They simply disagreed whether an exception should be permitted in the rare case that an applicant cannot describe his invention in non-process terms. Petitioner has presented no evidence that inventions qualifying for that exception are common. To the contrary, there is every reason to expect that, given advances in analytical technology, the number of affected patents is small and will diminish in the future. Moreover, this case is a particularly poor vehicle for deciding whether a "rule of necessity" is needed, as it is undisputed that petitioner's patent would not qualify for the exception even if this Court were to recognize it.

For that reason, petitioner is forced to argue for an even broader rule than was advocated by the dissenters below, one that would dispense entirely with what all the judges of the Federal Circuit agree has been the general rule for more than a century. With nary a single member of that specialized court advocating petitioner's view of patent law, petitioner's plea for review by this Court should be rejected.

I. The Question Presented Does Not Arise On the Facts of this Case.

Petitioner asks this Court to determine whether "product-by-process claims are . . . infringed by an identical product made by a different process." Pet. i. That question does not arise on the facts of this case because respondents' Crystal B generic drug is not "an identical product" to the Crystal A compound claimed in the '507 patent. Pet. App. 34. Consequently, deciding the question presented would not affect the disposition of this case.

Petitioner does not dispute in this Court that the two crystalline forms of cedfinir are distinct substances and that respondents' use of Crystal B would not infringe a patent for Crystal A, either literally or by equivalence. *See Lupin*, 484 F. Supp. 2d at 458; Pet. App. 93-102. In addition, the district court found, and petitioner does not dispute here, that the compound described by the Claim 1 x-ray fingerprint is Crystal A. *Lupin*, 484 F. Supp. 2d at 458. As a result, petitioner's only hope of prevailing was to convince the court that its product-by-process claims encompass both Crystal A and Crystal B, even though its traditional product claim does not.

The district court, however, found the product-by-process claims were no broader than the product

claim and are likewise limited to Crystal A. *Lupin*, 484 F. Supp. 2d at 454-59; Pet. App. 13-17. The court observed that all of the claims in the patent claim "Crystalline [cefdinir]," which Claim 1 identified as consisting of a compound with the x-ray signature of Crystal A. *Lupin*, 484 F. Supp. 2d at 454. Petitioner knew how to claim Crystal B as well, having done so by name and x-ray signature in its Japanese application. Pet. App. 8-9, 14-15. Petitioner intentionally chose to abandon Crystal B in its U.S. patent.[5] *Id.* The patent's "specification and prosecution history, read carefully together with the claims," the court held, "announce 'Crystal A' as the '507 patent's invention." *Lupin*, 484 F. Supp. 2d at 459.

The Federal Circuit's affirmance of that holding constituted an entirely independent ground for rejecting petitioner's infringement claims. *See* Pet. App. 36-37 (holding that district court "properly concluded on summary judgment that Lupin's cefdinir product did not infringe claims 1-5 literally or claims 2-5 by equivalency"). No member of the en banc court challenged that conclusion, and petitioner does not challenge (or even mention) it here. Moreover, even if it did, any such challenge would fall outside the scope of the question presented and pose no certworthy question of broader legal significance. *See* Pet. i; *Matsushita Elec. Indus. Co. v. Epstein*, 516 U.S. 367, 379 n.5 (1996).

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[5] The expired cefdinir prior art patent, the '334 patent, described in Example 14 the final product as "obtained crystals" of cefdinir; since this cefdinir shared the same characteristics as Crystal B in the Japanese application, respondent could not patent the identical crystal twice in the U.S. *See, e.g.*, 35 U.S.C. § 102(b) (novelty requirement).

II. The Petition Does Not Present a Question of Recurring Importance.

Petitioner has also failed to demonstrate that the dispute among the members of the Federal Circuit involved a question of recurring and lasting importance.

1. All of the judges agreed that, as a general rule, "[e]very patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process." *BASF*, 111 U.S. at 310; *see also* Pet. App. 21-22 (en banc majority) (quoting *BASF* as establishing standard); *id.* at 68 (Newman, J., dissenting) (acknowledging that statement in *BASF* "is indeed the general rule").[6] Three judges, however, argued that there should be "an exception to the general rule," Pet. App. 45 (Newman, J., dissenting), which would apply "only" when a "product is new and its structure is not fully or readily known," *id.*

But there is no reason to believe that many patents would fall within this "rule of necessity," which the dissent itself described as "narrow." Pet. App. 86 (Newman, J., dissenting). Indeed, Judge Newman conceded that, historically, "the rule of necessity was seldom applied," Pet. App. 48-49, and remains "rarely invoked" today, *id.* at 59. It thus would, at most, apply to a "small . . . class of inventions," *id.* at 40, incapable of non-process description despite advances in analytical technology that Judge Lourie recognized may have already rendered the exception unneces-

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[6] *See also* Pet. App. 54 (Newman, J., dissenting) (acknowledging "general rule").

sary, *see id.* at 88 (Lourie, J., dissenting) ("It may be that with today's analytical techniques there is little need for product-by-process claims.").

Petitioner stands alone before this Court insisting that the question presented by its petition is of general importance to the patent-holding community. Although its licensee sold a profitable brand-name drug under the '507 patent, and was a party to this action below, it has not joined in the petition. Nor has a single patent-holder or organization come forward to file an amicus brief in support of the petition.[7] And perhaps most tellingly, although a purported intracircuit conflict over the scope of product-by-process claims endured within the Federal Circuit for more than 17 years prior to the decision in this case, petitioner has not identified a single prior petition to this Court arguing that the conflict created an untenable practical burden on patent-holders. That the Federal Circuit now applies only a single, consistent rule provides even greater reason to think that the question presented has little practical impact.

Unsurprisingly, in the vast majority of cases, an inventor can fully protect its invention by describing it in non-process terms, as petitioner did here in claiming Crystal A, and as it did in its Japanese application attempting to claim Crystal B. If there are, indeed, inventions that, despite advances in technology, can only be described in process terms, the decision in this case still affords them considerable patent protection. If experience shows that the

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[7] The patent bar has not hesitated in the past to inform the Court when it views a decision of the Federal Circuit as addressing a question of recurring importance worthy of this Court's attention. *See, e.g.*, Docket for *Bilski v. Kappos*, No. 08-964 (nine cert-stage *amicus* briefs filed).

Federal Circuit's rule provides inadequate protection in a significant number of applications, this Court will have ample opportunity to review it in a future case where, unlike here, it might actually be dispositive.

2. Petitioner's various complaints about other aspects of the decision below, and the process by which it was reached, do not render an otherwise uncertworthy question suitable for this Court's attention.

First, petitioner complains that the Federal Circuit decided the product-by-process question *sua sponte* without ordering supplemental briefing or holding oral argument on the question. Pet. 8-11. But petitioner's Question Presented does not ask this Court to decide whether the procedures followed here were lawful, *see* Pet. i, and they plainly were. Petitioner does not dispute that en banc review was appropriate to resolve any intracircuit split. And while it alleges that the Court did not follow its self-imposed Internal Operating Procedures (IOP), it acknowledges that the IOP itself states that departures from it are permitted. Pet. 9; *see also* Fed. Cir. IOP 1 ("The court reserves the right to depart from a provision in the IOPs when circumstances require."). Nor does petitioner point to any other source of law precluding courts from circulating opinions prior to publication for en banc consideration,[8] a routine practice in other

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[8] Although petitioner makes no mention of it, Judge Newman suggested that the court had violated Rules 34 and 35, Fed. R. App. P. *See* Pet. App. 40-42. But Rule 35 simply states *when* en banc review is appropriate and says nothing about *how* it shall be conducted. And Rule 34 simply addresses oral argument (not briefing) before the three-judge panel, not the procedures for rehearing cases or issues en banc. The en banc court is no more

circuits. *See, e.g.*, 7th Cir. R. 40(e); *Ionics, Inc. v. Elmwood Sensors, Inc.*, 110 F.3d 184, 187 n.3 (1st Cir. 1997); *United States v. Coffin*, 76 F.3d 494, 496 n.1 (2d Cir. 1996). Nor has petitioner shown any real prejudice from the court's procedures. While petitioner hypothesizes that the court would have benefited from additional briefing from the parties, it offers no arguments in its petition that were not thoroughly considered. Likewise, although petitioner asserts that the Federal Circuit's actions prevented *amici* representing the holders of "thousands of patent claims" to participate in the case, Pet. 10, none has come forward in support of the petition to this Court despite ample opportunity to do so. *Cf. supra* n.7.

Second, petitioner also criticizes the panel's construction of the term "obtainable by" in the patent. *See* Pet. § V. But, again, petitioner does not ask this Court to review that holding. *See id.* at i. Nor is the proper construction of "obtainable by" certworthy in its own right. Petitioner claims that the panel's construction of that term "puts thousands of current patents at risk," Pet. 29, because the phrase "obtainable by" has been included in "over 11,000 patents" over the past twenty years, *id.* at n.13. That figure is incorrect,[9] as is the conclusion

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required by Rule 34 to hold additional oral argument upon rehearing en banc than is the original three-judge panel required to hold a second oral argument when it grants panel rehearing.

[9] Respondent conducted the same search, using the same database, and found only 2,600 patents issued between August 26, 1989, and August 26, 2009, containing the phrase "obtainable by" in the "claims." It appears that petitioner's count includes not only issued patents, but also applications. To put

drawn from it. The panel did not hold that "obtainable by" automatically signals a product-by-process claim. To the contrary, the panel reached its conclusion in this case based on the language of the claim, the text of the specification, the relationship among different claims, and the prosecution history which showed petitioner's "acquiescence to the PTO's view that the process elements of claims 2-5 are critical parts of those claims." Pet. App. 28. Whether that patent-specific determination was correct does not warrant this Court's review.

III. The Decision Below Was Correct.

Review is further unwarranted because the decision below was correct, and because the rule proposed by petitioner is unprecedented and inconsistent with both this Court's decisions and longstanding principles of patent law.

As noted above, petitioner does not ask this Court to adopt the limited "rule of necessity" advanced by the dissent below. Instead, petitioner claims, as it must, that patent applicants are free in all cases to describe their inventions solely in terms of the process that produces the product and, if they do, are entitled to a monopoly over any new product that they can later show would be produced by such a process. Petitioner does not claim that this Court has ever adopted such a sweeping rule, arguing instead only that the cases cited by the majority below do not preclude petitioner's expansive view of product-by-process claims. But even the dissenters below recognized that this is not so, and that for more than a century, this Court has adhered to the general prin-

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both numbers in context, during the same period, the PTO issued more than 2.7 million utility and reissue patents.

ciple that product-by-process claims are limited to products produced by the process described in the patent. Pet. App. 67-68, 87. Petitioner provides no convincing reason for this Court to revisit that precedent now.

A. This Court Has Long Held That the Process Terms of Product-By-Process Claims Limit the Patent.

For more than a hundred years, this Court has consistently taught that product-by-process claims are limited by their process requirements.

As the Federal Circuit explained, this Court's *BASF* decision set forth the standard for infringement of product-by-process claims in clear and unequivocal terms:

> Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.

BASF, 111 U.S. at 310. The question arose in *BASF* with respect to a patent claim that read:

> "Artificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result."

Id. at 296. This Court held that the accused product did not infringe because it was prepared by a different process. *Id.* at 310.

Petitioner argues that the decision in *BASF* is limited to cases in which process terms are used to described an old, and therefore unpatentable, prod-

uct, pointing to a later passage in the opinion that suggests that the product described in the patent in *BASF* was not new. Pet. 18. But the language in the Court's opinion, quoted above, makes no such distinction. And, in fact, the portion of the opinion upon which petitioner relies provided an entirely independent, alternate ground for the decision. *See BASF*, 111 U.S. at 311 (discussing "another view of the case"). The principal ground for the decision was written on the assumption that the product claimed was in fact new. *See id.* at 310-11.[10]

Moreover, the Court's decision in *BASF* does not stand in isolation. Eight years earlier, in *Smith*, the Court construed a patent directed to artificial teeth, *see Smith*, 93 U.S. at 489-90, with a claim to a "'plate of hard rubber, or vulcanite, or its equivalent, for holding artificial teeth, or teeth and gums, substantially as described [in the specification].'" *Id.* at 493. The specification required a very particular process for making the product. *Id.* at 494. This Court interpreted the claim as a product "made in a defined manner," not one "separated from the process by which it is created. . . . The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed." *Id.* at 493.

Three years later, in *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222 (1880), this Court considered the question of infringement of this same

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[10] As noted below, the Court has given the same scope to product-by-process claims, both before and after *BASF*, in other cases in which there can be no dispute that the product at issue was new. *See, e.g., Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493-94, 501 (1876); *Plummer v. Sargent*, 120 U.S. 442, 448 (1887).

patent, and affirmed the district court's holding that a celluloid plate for artificial teeth prepared in a manner "wholly unlike that employed in making hard rubber or vulcanite," did not infringe. *Goodyear*, 102 U.S. at 229. To infringe, the Court held, either the stated "process of constructing the plate," or a "process equivalent thereto, must be employed." *Id.* at 226.[11]

The patent in *Merrill v. Yeomans*, 94 U.S. 568 (1876), required heavy hydrocarbon oils deodorized by a specific process. *Merrill*, 94 U.S. at 569-70. Applying "the well-settled rules of construing all instruments," the Court held that the process descriptions "must either refer to the process of making the oils for which the applicant is claming a patent, or they are intended to limit his claim for a patent for the product to that product only, when produced by treating the oils in the manner before described." *Id.* at 571.

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[11] Petitioner and the dissent below argue that the *Goodyear* cases did not involve product-by-process claims because the patent did not include any reference to the process. Pet. 18. This is incorrect. The plate at issue was a specific type of product based on a soft vulcanizable compound which is then hardened to hold the teeth and pins in place. *Smith*, 93 U.S. at 494. This Court interpreted the claim as a modern day product-by-process claim:

> The invention, then, is a product or manufacture made in a defined manner. It is not a product alone separated from the process by which it is created. . . . The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed.

Id. at 493. Contrary to Petitioner's sweeping assertion, the Court concluded both the process and the product were new and patentable. *Id.* at 493-94, 501.

In *Plummer*, the patent claimed the product of an improved process of bronzing or coloring iron. *Plummer*, 120 U.S. at 444-46. Affirming the judgment below, this Court observed that:

> [I]t may be assumed that the new article of manufacture called Tucker bronze is a product which results from the use of the process described in the patent, and not one which may be produced in any other way. So that, whatever likeness may appear between the product of the process described in the patent and the article made by the defendants, their identity is not established unless it is shown that they are made by the same process.

Id. at 448.[12]

And in *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938), the Court confirmed that "a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced." *Gen. Elec.*, 304 U.S. at 373 (footnote omitted). Quoting *BASF*, the decision reiterated

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[12] Judge Newman, in dissent, argued that these claims were limited to the process "to sustain validity of the patent in view of the . . . prior art." Pet. App. 74. However, if the product cannot be said to be new or distinguishable from the prior art except by reference to the process by which the product was made, then the resulting product is of the type where Judge Newman seeks to apply the "Rule of Necessity" exception. *Id.* at 37. The en banc majority rule below that, if an inventor chooses to claim the product in terms of its process, then that process "also governs the enforcement of the bounds of the patent right," Pet. App. 25, absolutely follows the logic of *Plummer*, *id.* at 22, mooting Judge Newman's concerns.

that, for a claim trying to distinguish a new product from the prior art by reference to a process, "'nothing can be held to infringe the [claim] which is not made by that process.'" *Id.*[13]

Finally, this Court expressed the same understanding of product-by-process claims in its more recent decision in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989). There, the Court considered whether a state statute was preempted by federal patent law. The state of Florida had made it unlawful for boat manufacturers to:

> use the direct molding process to duplicate for the purpose of sale any manufactured vessel hull or component part of a vessel made by another without the written permission of that other person.

Bonito, 489 U.S. at 144-45 (citation omitted). In the course of its Supremacy Clause decision, this Court likened the state statute to a product-by-process patent. *Id.* at 159. That comparison is apt only because the Florida statute, like federal product-by-process claims, protects against the creation of an identical product through a specified means. In particular, this Court explained, under the state law, "[l]ike the patentee, the beneficiary of the Florida statute may prevent a competitor from 'making' the product [by direct molding] and from 'selling' the product when it is produced in that fashion." *Id.* at 158. This is entirely consistent with the Federal Circuit's approach here, which obligated petitioner to

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[13] While the claim at issue was actually a product claim, the Court nonetheless considered whether an indefiniteness ruling could be avoided by construing the claim with reference to the process described in the specification.

prove the accused product was made by the claimed process.

B. The Federal Circuit's Ruling Does Not Require Construing Claims Differently For Validity and Infringement.

Unable to point to any decision of this Court adopting its view, petitioner instead is reduced to arguing that the decision below conflicts with this Court's authority at a higher level of generality. In particular, petitioner claims that the decision below conflicts with the general proposition of, "[t]hat which infringes, if later, would anticipate, if earlier." Pet. 2 (quoting *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) (internal quotation marks omitted)). The decision below violates that precept, petitioner argues, because it treats product-by-process claims as a *product* claim for purposes of patentability (since the PTO requires a product-by-process claim to be a new and patentable invention) but as a *process* claim for purposes of infringement (because it requires the use of the process described in the patent). Pet. 11. This argument is misguided as well.

The Federal Circuit's decision is completely consistent with the *Peters* principle: an invention that would infringe a product-by-process patent (*i.e.*, an invention producing the same product by the same process) would anticipate the patent if invented earlier. If the patentee can only distinguish a product by reference to a process, then "that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor." Pet. App. 25.

In this case, for example, if a company other than petitioner produced Crystal A by the process described in the '507 patent before that patent's priority date, the invention would have anticipated petitioner's patent claim; and the same product produced by that same process would infringe the '507 patent if practiced later.[14]

Petitioner nonetheless persists that the basic premise of *Peters* is violated because, it insists, the decision below treats product-by-process claims as product claims for patentability, but as process claims for infringement. This is wrong in two respects.

First, it is wrong to say that the Federal Circuit treats product-by-process claims as product claims for purposes of patentability and validity, but as process claims for infringement. The decision makes abundantly clear that product-by-process claims are product claims at both stages. In deciding patentability, the PTO and the courts apply the "ordinary requirements of patentability." Pet. App. 25. Moreover, the Federal Circuit made equally clear that the resulting patent is for the product, not simply the process, although the product must be made in the way described in the patent. *See id.* The distinction between having a patent for a product made a particular way, and simply having a patent for that process, is of real significance. For example, one who

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[14] This, in fact, is what occurred in *Plummer*; since the accused infringer was practicing a prior art process different from the one in the patent, it "seems necessarily to follow from this view either that the Tucker patents are void by reason of anticipation practiced by Brocksieper, or that the patented process and product must be restricted to exactly what is described." *Plummer*, 120 U.S. at 449.

has not manufactured a product, but simply sells it, may be sued for violating a product-by-process patent, but not for infringing a pure process patent. *See Joy Tech. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) ("A method claim is directly infringed only by one practicing the patented method."); *Cardiac Pacemakers Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1358-59 (Fed. Cir. 2009).[15]

Second, it is simply untrue that, under the Federal Circuit's interpretation, the PTO gives product-by-process claims a broader construction (unlimited by process terms) than does a court in litigation. As a general matter, the PTO does not construe the scope of the patents it issues. It is solely responsible for determining whether the application meets the criteria for patentability. And, as the Federal Circuit explained, because product-by-process claims are a form of product claim, the PTO must decide whether the product claimed meets the traditional requirements for patentability. Pet. App. 25. The process terms have no bearing on that question and, for that reason, are not the focus of PTO's attention. But that does not mean that the PTO construes a resulting

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[15] Even more significantly, before Congress enacted 35 U.S.C. § 271(g) in 1988, patent-holders could not sue to enforce process patents when the process was practiced outside the U.S. But patent-holders could use product-by-process claims to stop those who made infringing products abroad and then imported them. Congress enacted § 271(g) to prevent competitors from avoiding a process patent by producing products outside the United States and then importing them. *See, e.g.*, S. Rep. No. 100-388, at 33 (1988); H.R. Conf. Rep. No. 100-576, at 1085-87 (1988), *reprinted in* 1988 U.S.C.C.A.N. 1574, 2118-20. This change may explain the diminishing significance of product-by-process claims. The '507 patent here was filed in August 1988, and claims priority to a Japanese patent application filed in 1987.

product-by-process claim as encompassing the product regardless of how it is made (a question that simply does not arise during the course of the PTO's work).[16] Instead, it simply shows that the process restrictions—while limiting the scope of the patent—are generally of lesser practical importance to whether the patent should issue,[17] which is the only question the PTO is charged with deciding.

In any event, as described above, any perceived asymmetry has been accepted by this Court for more than a century. Indeed, although the dissent below complained at length that the decision in this case created an untenable disparity in the treatment of product-by-process claims at the patentability and infringement stages, it did not dispute that the disparity necessarily arises under what it conceded was the "general rule" described in cases like *BASF*. *See* Pet. App. 45, 54.

C. The Federal Circuit's General Rule Is Consistent With General Patent Principles and Policy.

Limiting product-by-process claims in accordance with their process terms is entirely consistent with basic patent principles and the policy underlying federal patent law.

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[16] Nevertheless, the PTO has considered whether process elements were found in the prior art in the context of product-by-process claims. *See In re Hirao*, 535 F.2d 67, 69-70 (C.C.P.A. 1976); *In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973).

[17] It has long been recognized that "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535 (C.C.P.A. 1972).

It is a "'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The claims control in the doctrine of equivalents analysis as well. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). Thus, a "patent confers the right to exclude others from making, using, or selling the invention defined by the claims." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985). The courts' focus on claim language ensures that the public receives the benefits of full disclosure of the invention in exchange for the legal monopoly endowed upon the inventor. *See Enzo Biochem., Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 971 (Fed. Cir. 2002).

Freeing product-by-process claims from their process limitations would violate these basic principles.

First, it would undermine the "definitional and public-notice functions of the statutory claiming requirement." *See Warner-Jenkinson*, 520 U.S. at 29. As the court recognized below, it would grant a monopoly in a product that the patent has not, in fact, fully disclosed. *See* Pet. App. 26. Indeed, petitioner's proposed rule would create a substantial disincentive for full disclosure. As at least one commentator has noted, "[b]roadening the scope of product-by-process claims . . . would reduce incentives for inventors to attempt characterization of the claimed invention." Gary Newson, *Product-by-Process Patent Claims: Arguing for a Return to Necessity and a Reduction in the Scope of Protection*, 40 ARIZ. ST. L. J. 327, 338 (2008).

Second, petitioner's proposal would divorce the infringement analysis from the terms of the claim

itself. Under petitioner's view, in order to determine whether a patent claim is infringed, it would never be enough to simply compare the claims in the patent with the allegedly infringing product and process. Instead, one would have to follow the procedures described; produce an actual product; and then compare it to the alleged infringer's wares. But the Federal Circuit has long held that "it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process . . . ." *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994).

Third, allowing patent-holders to substitute an unidentified proxy product or undisclosed product characterizations as claim boundaries, to the exclusion of clearly identified and definite process-based descriptions actually found in the patent claims, would create substantial practical difficulties for the PTO as well as patent-holders and their competitors. The product-by-process format has vexed PTO examiners, because the PTO cannot "manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *Brown*, 459 F.2d at 535.

Those concerned with avoiding patent infringement face the same unnecessary costs and uncertainty. As this Court stated long ago in *Merrill*, "[t]he public should not be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights." *Merrill*, 94 U.S. at 573; *see also United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942); *McClain v. Ortmayer*, 141 U.S. 419, 424 (1891). But under petitioner's rule, rather than simply examining the text of the patent, a company

concerned about potential infringement must instead follow the process steps (often with significant difficulty and expense) to produce what they hope is the claimed product (and if it is, possibly commit an act of infringement by performing that process), then compare that product through some *other* technique perhaps nowhere mentioned in the patent to determine whether it is the same as the one the company intends to produce. The patent statute has never contemplated such an ordeal, which would discourage the "exploitation of unpatented designs and innovations," upon which our free market depends. *Bonito*, 489 U.S. at 151.

Moreover, the same burdens would be imposed on courts called upon to adjudicate product-by-process claims, the scope of which can be determined only through laboratory experiments rather than through a close reading of the text and history of the patent.

Fourth, as this case illustrates, unmooring patent protection from the disclosures in the patent risks giving patent-holders a protection "wider in its scope than the original actual invention of [the inventors], and wider than anything indicated in the specification of the original patent." *BASF*, 111 U.S. at 313. Here petitioner's traditional product claim was clearly limited by its reference to an x-ray signature to Crystal A. Yet because of the inherent ambiguity in its product-by-process claims, petitioner attempted to assert that Claims 2-5 patented a broader invention. In fact, in the district court, petitioner argued that, after the '507 patent issued, other inventors managed to use (in whole or in part) some of the Crystal A process steps to produce Crystal B. Petitioner thus insisted that its claims must cover Crys-

tal A and Crystal B. *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 769-770, 774 (N.D. Ill. 2007).

The Federal Circuit's approach to interpretation of product-by-process claims, on the other hand, is in accord with the statute (only claims can be infringed, 35 U.S.C. § 271; patentees must use the claims to define the invention, 35 U.S.C. § 112 ¶ 2; *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372-4 (1996)); with this Court's guiding principles (each and every claim element is presumptively material: *Warner-Jenkinson*, 520 U.S. at 30); and provides clear guidelines that do not make claim interpretation contingent upon resolving factual disputes about whether a given product is old or new, or an appropriate substitute for the claims or not.

D. Although It Makes No Difference In This Case, The Federal Circuit Properly Refused to Recognize a "Rule of Necessity" Exception.

Whether or not the general rule for product-by-process claims accepted by all the judges below should be subject to an exception for inventions incapable of description through non-process terms ultimately makes no difference in this case. *See supra* at 7, 14-15. But the Federal Circuit nonetheless was correct to refuse to recognize a rule of necessity exception.

The perceived need to protect inventions that cannot be described in non-process terms does nothing to diminish the legal and practical difficulties of divorcing product-by-process claims from the constraints of their process terms. In fact, some of the problems are most acute in precisely the cases in which the rule of necessity would apply, including the

difficulty of deciding whether a similar-seeming product made by a different process is actually identical to the product described in the patent. If the exception applies, it is because the product cannot be identified except by examining the process through which it is made. But if that is true, how could a district court ever ascertain that a product made by process Z is "really the same as the patented compound" made by process Y without looking at the process conditions used to make the product? Pet. App. 25-26.

This Court, in fact, confronted this very issue in *Plummer*, 120 U.S. at 448, for a unique product called "Tucker bronze." The surface of the iron product was described as resulting from a very specific process that leaves a "firm film, which is very durable, and gives the iron a highly ornamental appearance, like that of bronze." *Id.* at 443. The exact composition of the film was unknown and not stated. This Court recognized that the accused product could not be shown to be *identical* to the patented "Tucker bronze" product "unless it is shown that they are made by the same process." *Id.*[18]

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[18] It is at least theoretically possible that advances in analytical technology could permit a patent-holder to show that a product made by a different process is, in fact, the same as that claimed in a product-by-process patent, even though it was impossible to describe the patented product in non-process terms at the time of the patent application. But if and when that happens, the patentee may apply for a broader reissue claim without the limiting process elements, as the patent-holder in *Scripps* eventually did. *See* 35 U.S.C. § 251; *Scripps Clinic & Research Found. v. Genentech, Inc.*, 707 F. Supp. 1547, 1555-56, 1560 (N.D. Cal. 1989); *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1299, 1303 (Fed. Cir. 1992) (Rader, J., concurring). That approach remains open to patent-holders today.

At the same time, limiting the types of cases in which an unrestricted product-by-process claim will be recognized raises difficult line-drawing problems of its own. The dissent suggested no standard for evaluating whether the exception should apply in any particular case, other than to state that it should be available when a product's "structure is not fully or readily known, such that its definition as a product is aided by referring to how it was made." Pet. App. 45. Applying the exception would therefore require extensive satellite litigation over its applicability under an inherently vague standard. Moreover, it would engender substantial uncertainty about the scope of patent monopolies, deterring the introduction of useful products into the market (including, for example, desperately needed, less expensive generic drugs) that benefit the nation and its economy.

As noted above, the Federal Circuit's decision here still allows significant protections for those who might fall within a rule of necessity exception, including pharmaceutical and biotech companies. Pet. App. 25. If more is required, if the needs of emerging technology require rethinking rules that have seen this country through the last century of dramatic innovation and discovery, those arguments are "best addressed to Congress, not this Court." *See Warner-Jenkinson*, 520 U.S. at 28.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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No. 09-335

In The Supreme Court of the United States

ASTELLAS PHARMA, INC.,

Petitioner,

v.

LUPIN LIMITED, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

RESPONDENT SANDOZ INC.'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit correctly applied established precedent in construing all claims of the Astellas patent to require the Crystal A form of cefdinir, whose structure was known and described by the patentee?

PARTIES TO THE PROCEEDINGS AND CORPORATE DISCLOSURE STATEMENT

The parties to the proceedings are: Petitioner/ Appellant Astellas Pharma, Inc. and Respondents/ Appellees Lupin Ltd., Lupin Pharmaceuticals, Inc., Sandoz Inc., Sandoz GmbH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical. Abbott Laboratories was an appellant below, but has not joined in the petition for certiorari.

Pursuant to the Court's Rule 29.6, Sandoz Inc. states that Novartis AG is the ultimate parent company of Sandoz Inc., owning 100% of Sandoz Inc. and trading on the New York Stock Exchange under the ticker symbol NVS.

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INTRODUCTION

This decision turned on claim construction of the term cefdinir. The Federal Circuit properly construed each of the claims in the Astellas '507 patent to require the Crystal A form of cefdinir, whose structure was known and described by the patentee in the '507 patent and in its earlier Japanese patent application. Based on that ruling alone, the panel affirmed the Northern District of Illinois's denial of a preliminary injunction sought by Astellas against defendants' Crystal B products.

Astellas's petition for a writ of certiorari ignores the dispositive Crystal A holding by the panel, and instead focuses on the Federal Circuit's decision to go en banc to further address its internal product-by-process dispute, which plays out in Section III.A.2 of the opinion and the dissent. Presenting one holding without the other portrays a heavily skewed picture, especially since the en banc court left standing the panel's Crystal A holding. In the end, Astellas's failure to contest the panel's holding for Crystal A in every patent claim means that the outcome here would be the same regardless of how the product-by-process claim issue is resolved. Because of that crucial fact, this case presents a poor vehicle for the Court's review of product-by-process claims.

The Federal Circuit, moreover, properly acted within its authority to take this case *sua sponte* en banc. Its actions are consistent with the rules of

practice and procedure that have been approved by the Court and enacted by Congress. Requiring otherwise rigid procedures would unduly hamper circuit en banc resolution of issues.

Thus, this is not a proper case for grant of certiorari.

STATEMENT OF THE CASE

Astellas Pharma, Inc. ("Astellas") is the assignee of U.S. Patent No. 4,935,507 ("the '507 patent"). Astellas and its licensee, Abbott Laboratories, asserted patent claims 1–5 against numerous defendants in two separate courts. Astellas sued Sandoz Inc. ("Sandoz") and others in the Northern District of Illinois and was a declaratory judgment defendant against Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") in the Eastern District of Virginia.

Each of the five claims of the '507 patent is directed to a crystalline form of the pharmaceutical cefdinir. Structure claim 1 recites only the crystalline form of cefdinir while claims 2–5 recite the crystalline form of cefdinir obtainable by certain process steps.

On April 27, 2007, the United States District Court for the Eastern District of Virginia determined that the asserted claims were limited to only one crystalline form of cefdinir, Crystal A. *Lupin Ltd. v. Abbott Labs.*, 484 F. Supp. 2d 448, 466 (E.D. Va.

2007). Based on that claim construction, the court granted Lupin's motion for summary judgment of noninfringement on June 14, 2007. *Lupin Ltd. v. Abbott Labs.*, 491 F. Supp. 2d 563, 571 (E.D. Va. 2007).

In the United States District Court for the Northern District of Illinois, Astellas, Sandoz, and the other defendants agreed to be bound by the Eastern District of Virginia's claim construction, and on May 3, 2007, after a two-day hearing, the court denied Astellas's motion for a preliminary injunction against Sandoz and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"). *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 770, 776 (N.D. Ill. 2007).

Without relying upon product-by-process claim analyses, and after reviewing evidence of the crystalline structure of both Crystal A and Crystal B, the Illinois district court determined that Astellas's claims, all of which required the Crystal A form of cefdinir, do not cover Sandoz's Crystal B cefdinir product, either literally or under the doctrine of equivalents. *Id.* at 771, 773–76. The district court denied the preliminary injunction because it found that it was unlikely that Astellas would be able to prove that Sandoz would infringe the '507 patent. *Id.* at 776.

Astellas appealed both the Illinois and the Virginia district court decisions to the Federal Circuit. In a single opinion, the Federal Circuit panel

affirmed the lower courts' holdings that each of the claims at issue was limited to Crystal A:

> Given the exclusive focus on Crystal A in the specification as well as the prosecution history of the '507 patent, the Eastern District of Virginia properly limited "crystalline" in claims 1-5 to "Crystal A."

Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1291 (Fed. Cir. 2009). Accordingly, the Federal Circuit affirmed the grant of summary judgment of no infringement by Lupin, and affirmed the denial of the preliminary injunction against Sandoz and Teva based on claim construction. *Id.* at 1297–99.

The Federal Circuit then took this case partially en banc to address a unique type of product-by-process claims in Section III.A.2. *Id.* at 1291–95.

REASONS FOR DENYING THE PETITION

I. ASTELLAS DOES NOT DISPUTE THAT THE FEDERAL CIRCUIT PROPERLY FOLLOWED THE COURT'S CLAIM CONSTRUCTION PRECEDENT

The Federal Circuit applied well settled law of claim construction in affirming the finding that the claims of the '507 patent are limited to the Crystal A form of cefdinir. In its petition, Astellas does not dispute that the claim term crystalline cefdinir, which appears in every claim of the '507 patent, is limited

to Crystal A. This concession alone is reason to deny the petition.

A. The '507 Patent Characterizes The Invention As Crystal A, Which Is Determinative Of The Case

According to statute, the claims must "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶2 (1975). Indeed, the Court stressed long ago the importance and purpose of patent claims: "[t]he claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." *White v. Dunbar*, 119 U.S. 47, 52 (1886). Hence, it is a fundamental tenet of patent law that the wording of the claims determines the scope of the patent. *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1373 (Fed. Cir. 2008).

Here, all five of the asserted claims contain the term "Crystalline 7-[2-(2-a minothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cepham-4-carboxylic acid (syn isomer)," which is the chemical name for cefdinir. *Abbott Labs.*, 566 F.3d at 1286.

There are at least two forms of cefdinir; one form is known as Crystal A and the other form is known as Crystal B. *Id.* at 1287. The two forms are

distinguished by their infrared ("IR")-absorption wavelengths and powder X-ray diffraction ("PXRD") angles and intensities: Crystal A can be described by three IR wavelengths and sixteen PXRD angles and intensities, while Crystal B can be described by five IR wavelengths and twenty-one PXRD angles and intensities. *Id.*

The disclosure of the '507 patent compels construing "crystalline cefdinir" to mean "Crystal A." The specification refers to Crystal A thirty-four times but notably makes no mention of any other form of crystalline cefdinir. '507 Patent col.2 l.2–col.13 l.67. According to the specification Crystal A is the "present invention":

> After an intensive study, the inventors of the present invention succeeded in obtaining the compound (I) as a special crystalline form, i.e. Crystal A . . . .

Id. at col.1 ll.34–36. Crystal A is described repeatedly in the specification as showing seven distinguishing "peaks" located at specific angles in a PXRD pattern. *See, e.g.*, *id.* at col.1 ll.49–66; col.12 l.48–col.13 l.3; and Fig.1; *see also Abbott Labs.*, 566 F.3d at 1289–90. No other crystal is disclosed. *See* '507 patent; *see also Abbott Labs.*, 566 F.3d at 1289.

The Federal Circuit agreed with the Virginia district court that claim 1 was limited to Crystal A because the specification repeatedly referred to "Crystal A of the compound (I) of the present invention," and it offered no suggestion that the recited processes could produce Crystal B. *Abbott*

Labs., 566 F.3d at 1289. Abbott's disavowal of Crystal B further supported the court's decision to limit the claim to Crystal A. *Id.* Abbott had successfully claimed Crystal B in a Japanese priority application, and thus knew how to claim Crystal B had it so desired. *Id.* Yet, in its U.S. patent application, Abbott removed all support for Crystal B in the specification, only disclosing Crystal A. *Id.*

Regarding the four other asserted claims 2–5, the court concluded that they also were limited to Crystal A because the "intrinsic evidence, including the prosecution history and [the] priority [Japanese] application, evince[d] a clear intention to limit the [asserted] patent to Crystal A." *Id.* at 1290. Because all the claims were limited to Crystal A, the process used to make them and whether that process was further limiting to the claims would not have changed the decision. *Id.* at 1291. *Cf. id.* at 1320 (Lourie, J., dissenting) ("[C]laim 1 of the Abbott patent is a claim to a compound, not only by name, but also by certain of its characteristics. A claim to a product defined by its characteristics or properties surely is a proper claim.").

B. Based On Claim Construction, The Federal Circuit Affirmed No Likelihood Of Infringement By Sandoz's Crystal B Product

Because the Federal Circuit found that all five of the asserted claims were limited to Crystal A, *id.* at

1289–90, the court affirmed the Illinois district court's denial of a preliminary injunction against Sandoz and Teva, because Abbott would most likely not be able to prove infringement: "Abbott was not likely to show [that] Sandoz and Teva's products contained any Crystal A at all." *Id.* at 1299. The court also affirmed the summary judgment finding of no infringement by Lupin due to the limiting of the claims to Crystal A. *Id.* at 1298. Therefore, the court found for the respondents on a completely separate basis from the product-by-process issue on which Astellas exclusively focuses in its petition for a writ of certiorari. *Id.* at 1297–99.

By failing to address the Federal Circuit's construction of claims 1–5, the petition paints an incomplete picture of the decision below. (Pet. Br. at 11–27); *Abbott Labs.*, 566 F.3d at 1289–91. Notably, the en banc portion, Section III.A.2, left standing the panel's case-dispositive holding that each of the claims of the '507 patent is limited to the Crystal A form of cefdinir. Astellas has not petitioned the Court on this case-controlling issue.

For these reasons, the case presents a poor vehicle to review product-by-process claims and the Court should deny the petition for a writ of certiorari.

II. ARTICLE III COURTS HAVE THE POWER TO MAKE AND INTERPRET THEIR OWN OPERATING PROCEDURES

Sua sponte resolution of an issue en banc at the circuit level is neither improper nor unusual.[1] Congress enacted 28 U.S.C. § 2071(a) (1988), which states that "all courts established by Act of Congress may from time to time prescribe rules for the conduct of their business." These rules only need to be consistent with the rules of practice and procedure and rules of evidence that the Supreme Court prescribes and submits to Congress. *Id.* at §§ 2071, 2072.

In accordance with 28 U.S.C. § 2071(a), the Federal Circuit promulgated Internal Operating Procedures ("IOPs"). Internal Operating Procedure 14.3 specifically permits that "hearing en banc following hearing by a panel of judges, but before the entry of judgment and opinion(s) by the panel, may be ordered sua sponte." The IOP further states that after a *sua sponte* petition for hearing en banc is granted, the "clerk shall provide notice that a majority of the

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[1] Several circuits may hear cases en banc without providing notice to the public and/or receiving additional briefing from the parties or the public. *See, e.g.*, 2d Cir. L.R. 35 (no notice requirement for hearing a case en banc); 3d Cir. IOP 9.6.3 (notice to parties may be requested but is not necessary); 4th Cir. L.R. 35 (no notice requirement for hearing a case en banc); 9th Cir. Advisory Committee Note to Rules 35–1 to 35–3; D.C. Cir. Internal Procedures XIII(B)(2) ("On occasion, only the original briefs have been considered," and "any active judge of the Court . . . may suggest that a case be reheard en banc.").

judges . . . has acted under 28 U.S.C. § 46 and Fed. R. App. P. 35(a) to order the appeal to be heard en banc, and indicate any questions the court may wish the parties and amici to address." Fed. Cir. IOP 14.3. Further, IOP 14.3 notes that "[a]dditional briefing and oral argument will be ordered as appropriate." *Id.*

The IOP does not contain a timing requirement for notice, and the requirement for briefing is "as appropriate" to the Federal Circuit. *Id.* Hence, where the court does not believe it needs additional briefing or oral argument to further aid in the decision, contemporaneous notice of en banc review with the court's decision is sufficient for compliance with the IOP. *See* Fed. Cir. IOP 14.3(c).

Regardless, the very first IOP states: "[t]he court reserves the right to depart from a provision in the IOPs when circumstances require." Fed. Cir. IOP 1.1. Thus, under any interpretation of the IOPs, the Federal Circuit was operating well within its authority.[2] As noted by Astellas, the Federal Circuit

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[2] Other circuits similarly state that they may depart from their operating procedures. For example, the Sixth Circuit states that its operating procedures "are not rules" and that "[i]n the interest of expediting decision or for other good cause, the Court may suspend the requirements of these [operating procedures]." 6th Cir. L.R. 2. Similarly, the Seventh Circuit asserts that the court may dispense with its operating procedures in particular cases; "[l]itigants acquire no rights under these procedures." 7th Cir. L.R. 2. The Tenth, Eleventh, and District of Columbia Circuits also contain provisions that

(Continued on following page)

has given contemporaneous notice before under IOP 14.3 (Pet. Br. at 9).

Moreover, the Supreme Court typically does not review whether courts have complied with their own operating procedures. As a general principle, "it is always within the discretion of a court or an administrative agency to relax or modify its procedural rules adopted for the orderly transaction of business before it. . . ." *Am. Farm Lines v. Black Ball Freight Serv.*, 397 U.S. 532, 539 (1970). The Court will not review a court's action with respect to its operating procedures "except upon a showing of substantial prejudice to the complaining party." *Id.* As the Federal Circuit's IOPs are procedural rules that it adopted for the orderly maintenance of its docket, it has the discretion to relax, modify, or circumvent the IOPs. Certainly, there is no abuse of discretion here.

Astellas's only alleged harm is the loss of opportunity for it and third-parties to comment on the product-by-process issue prior to the en banc ruling. However, Astellas's arguments in its petition parrot those of Judge Newman in *Scripps*, her dissent in the denial for rehearing of *Atlantic Thermoplastics*, and her dissent in this case, all of which the en banc court rejected and the Court now has before it. Thus, as Astellas puts it, "briefs from [Astellas and] the

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allow them to suspend their operating procedures or local rules. *See* 10th Cir. L.R. 2.1; 11th Cir. L.R. 2.1; D.C. Cir. R. 2.

public would have been an exercise in futility." (Pet. Br. at 9). Consequently, Astellas fails to allege a substantial prejudice in the Federal Circuit, and its procedural argument fails.

CONCLUSION

For the foregoing reasons, Sandoz Inc. respectfully requests that the Court deny certiorari.

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November 18, 2009

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit's *en banc* decision, which resolved an intra-circuit split in a manner consistent with this Court's precedent, properly found that claims reciting a product made by a certain process are not infringed by a product made by a different process?

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

The parties to the proceedings are: Petitioner/Appellant Astellas Pharma, Inc. and Respondents/Appellees Lupin Ltd., Lupin Pharmaceuticals, Inc., Sandoz Inc., Sandoz GmbH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical. Abbott Laboratories was an appellant below, but has not joined in the petition for *certiorari*.

As required by the Court's Rule 29.6:

Teva Pharmaceuticals USA, Inc. states that it is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd.

Teva Pharmaceutical Industries, Ltd. states that there is no parent corporation and no publicly held company that owns 10% or more of its stock.

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STATEMENT OF THE CASE

This is a patent litigation that involves a rarely-employed patent claim format known as a "product-by-process" claim. A "product-by-process" claim is a patent claim that recites a product made by a certain process. The issue presented in the petition is whether, in determining infringement of a product-by-process claim, the process terms recited in the claim serve as limitations, or whether the process terms must be ignored.

The Federal Circuit's *en banc* decision, *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009) (*en banc* in part) (App. 1), held that the process terms in product-by-process claims serve as limitations in determining infringement.

The facts of the case are set forth in the Federal Circuit's *en banc* decision below, and will not be repeated here.

REASONS WHY THE PETITION SHOULD BE DENIED

The petition for certiorari should be denied because the *en banc* decision below resolves any existing conflicts on an issue of patent law that arises only rarely. Moreover, the issue was correctly decided in accordance with this Court's precedent.

Petitioner argues that the Federal Circuit decision was wrong, relying on the arguments from the dissent below that eight of the eleven circuit judges sitting *en banc* found unconvincing. Petitioner fails to identify any issue or doctrinal conflict worthy of certiorari.

I. Certiorari Is Not Appropriate For A Narrow Decision On A Rarely-Arising Issue

Although the Court can, of course, grant certiorari to address important issues of Federal law, this is not such a case. The narrow issue of patent law addressed in this case is "whether [a product-by-process] claim is infringed by products made by processes other than the one claimed." App. 23. Courts rarely are forced to confront such an infringement analysis. Indeed, prior to the Federal Circuit's *en banc* decision below, the issue apparently had arisen only on two previous occasions in the twenty-five year history of the Court of Appeals for the Federal Circuit. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) (*overruled* by *Abbott*); *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992). In the seventeen years between *Atlantic Thermoplastics* and the *en banc* decision, only one other of the thousands of reported opinions issued by the Federal Circuit appears to have even indirectly ruled on the issue of infringement of a product-by-process claim.[1] The paucity of cases affected by the *en banc* decision underscores the rarity of this issue because the Federal Circuit heard all appeals in cases arising under the patent laws since its formation in 1982.

Petitioner alleges, without citation, that the decision below affects "thousands of active patent

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[1] *See Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352 (Fed. Cir. 2007) (ruling that if a particular dependent patent claim were construed as a product-by-process claim, the process steps of the base claim would be considered limitations in an infringement analysis).

claims." Pet. Br. 2. According to Petitioner, "product-by-process claims are more important now than they have ever been . . . in the areas of pharmaceuticals and biotechnology . . . ." Pet. Br. 29-30. Yet, not a single amicus filed a brief in support of Petitioner. Even Petitioner's co-appellant below, Abbott Laboratories – a noted pharmaceutical and biotechnology company with a direct stake in the outcome of this litigation – declined to join the petition for certiorari. Pet. Br. ii.

II. There Is No Doctrinal Conflict Worthy Of Certiorari

The Federal Circuit's *en banc* decision clarifies its prior *Scripps* and *Atlantic Thermoplastic* decisions, in keeping with this Court's precedent. The decision gives meaning to all of the words of a patent claim when determining infringement, including the recited process terms of product-by-process claims. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997).

Petitioner identifies three of this Court's decisions that it asserts conflict with the Federal Circuit's *en banc* decision: *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), *Peters v. Active Mfg. Co.*, 129 U.S. 530 (1889) and *White v. Dunbar*, 119 U.S. 47 (1886). *See* Pet. Br. 11-15, 16-17, 20-21. However, none of those cases set out or require a rule contrary to that announced in the decision below.

Petitioner also argues that certiorari is appropriate due to purported procedural irregularities in the Federal Circuit's decision to take the issue *en banc*. Petitioner's procedural arguments are a red herring, since the Federal Circuit acted within its operating

procedures to resolve the issues efficiently, and because additional briefing would have served no purpose.

Finally, Petitioner argues that the Federal Circuit's *en banc* decision conflicts with prior decisions of the Federal Circuit and other lower courts.[2] Even if that were so, it could not serve as a proper basis for certiorari since the Federal Circuit's *en banc* decision would settle any such prior conflict. Certiorari is rarely, if ever, granted to overturn an *en banc* decision which clarifies intra-circuit precedent. *See* E. Gressman, Supreme Court Practice, 253-54 (BNA Books 9th ed. 2007).

A. The Federal Circuit's *En Banc* Decision Is Correct, And Follows This Court's Precedent

The Federal Circuit's *en banc* decision holds that the recited process steps in product-by-process claims cannot be ignored, and serve to limit the scope of any claim for infringement. App. 26. This rule is well-settled and consistent with this Court's precedent.

First, this rule for the infringement of product-by-process claims squares precisely with this Court's general pronouncement that "[e]ach element contained

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[2] For example, Petitioner argues that the decision below improperly rewrites the claim language of claims 2-5 of the patent in suit. Pet. Br. 27-29. In essence, Petitioner argues that the claims should be interpreted as something other than product-by-process claims. This issue is irrelevant because it is outside the scope of the question Petitioner seeks to present to this Court. *See* Pet. Br. i.

in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkinson*, 520 U.S. at 29.

Second, this rule is also consistent with this Court's precedent on product-by-process claims in particular. For example, in *BASF*, when considering the infringement of a product-by-process claim in 1884, this Court stated:

> Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.

Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 310 (1884) ("*BASF*"). The Court concluded that "[u]nless that process will practically produce the defendant's article . . . [the patent-in-suit] is not infringed." *Id.* at 311.

The Federal Circuit's *en banc* decision correctly notes that other decisions of this Court also give meaning to the process that is recited in a product-by-process patent claim. App. 18-19. *See, e.g., Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493 (1876); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224 (1880); *The Wood-Paper Patent*, 90 U.S. 566, 596 (1874); *Plummer v. Sargent*, 120 U.S. 442, 448-450 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373-74 (1938).

The Federal Circuit rule also follows a long line of other circuit courts which reached the same conclusion as *BASF*:

> It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process.

Hide-Ite Leather Co. v. Fiber Prods. Co., 226 F. 34, 36 (1st Cir. 1915) (citing *BASF*, 111 U.S. at 312); *accord Downes v. Teter-Heany Development Co.*, 150 F. 122, 124 (3d Cir. 1907), *cert. denied*, 205 U.S. 543 (1907); *see also Buono v. Yankee Maid Dress Corp.*, 77 F.2d 274, 279 (2d Cir. 1935) (L. Hand, J.) (claims to a product of a machine or a process "would in that case not be infringed by anything but the product of the machine or of the process . . .").

1. *Bonito Boats* Confirms That Product-By-Process Claims Are Infringed By Products Made By The Recited Process

Petitioner argues that the Federal Circuit decision conflicts with this Court's decision in *Bonito Boats*. Pet. Br. 16-17, 20-21. Petitioner misreads that decision. *Bonito Boats* addressed the constitutionality of a Florida statute that prohibited using a particular method of making boat hulls and sale of the resulting boat hulls. The statute, which the Court said "resembles that of a so-called 'product-by-process' patent," was preempted by the patent laws since it granted boat hull manufacturers substantial control

over "the use of a particular process and the ***sale of an article created by that process*** . . . ." *Bonito Boats*, 489 U.S. at 158, n* (emphasis added). The Court stated:

> The statute makes "[i]t . . . unlawful for any person to use the direct molding process to duplicate for the purpose of sale any manufactured vessel hull or component part of a vessel made by another without the written permission of that other person." § 559.94(2). The statute also makes it unlawful for a person to "knowingly sell a vessel hull or component part of a vessel duplicated in violation of subsection (2)." § 559.94(3).

Id. at 144-5. Thus, the Court likened product-by-process patent claims to a statute that covered a product (vessel hulls) made by a particular process (direct molding). Since the statute was violated only when the specific process was used, the Federal Circuit's decision below is fully consistent with the discussion of product-by-process claims in *Bonito Boats*.

Petitioner argues that *Bonito Boats* somehow supports a rule that a product-by-process claim should be interpreted to ignore the recited process if the product is found to be new, but require the recited process if the product is old. Pet. Br. 16-17, 20-21. Petitioner relies on a single statement, in a footnote, that "a patent in the process may support a patent in the resulting product" if "the end product of the process is adequately defined and novel and nonobvious." *Bonito Boats*, 489 U.S. at 158, n*. The footnote says nothing about how product-by-process

patent claims should be interpreted for infringement or validity, and cannot be said to set forth a new rule with respect to "new" or "old" products. In short, *Bonito Boats* agrees that a product-by-process claim "'is one in which the product is defined at least in part in terms of the method or process by which it is made.'" *Id.* (quoting D. Chisum, Patents, § 8.05, p. 8-67 (1988)).

2. The Limited Infringement Holding In This Case Does Not Conflict With This Court's Precedent Relating To Validity

Unable to demonstrate that the Federal Circuit's decision below directly conflicts with prior precedent of this Court, or even of sister circuits from the days before the creation of the Federal Circuit, Petitioner contends that the Federal Circuit's *en banc* decision conflicts with this Court's decision in *Peters*, which reasons "[t]hat which infringes, if later, would anticipate, if earlier." Pet. Br. 12 (quoting *Peters*, 129 U.S. at 537 (1889)); *see also White*, 119 U.S. at 51 (a claim is not "a nose of wax which may be turned and twisted in any direction"). Petitioner argues that, under the rule of *Abbott*, "claims are now interpreted differently for validity purposes than for infringement purposes." Pet. Br. 11.

Petitioner's attempt to broaden the ruling of the decision below in order to find a conflict with precedent is unavailing. First and foremost, the *en banc* decision below neither states nor implies that the infringement rule creates any different interpretation of patent claims for validity analyses. The *en banc* decision below, and the district court decisions that it reviewed, were directed only to the issue of infringement, and

did not address validity. App. 23 ("The issue here is only whether such a claim is infringed by products made by processes other than the one claimed. This court holds that it is not."). Only infringement issues were considered and discussed below – not validity. This Court should decline Petitioner's invitation to disturb an infringement holding that follows this Court's overwhelming precedent, and should not address validity issues that go beyond the bounds of the narrow decision below.

Second, Petitioner relies on the Federal Circuit panel decision in *Atlantic Thermoplastics* to argue there is a conflict. Pet. Br. 13. However, *Atlantic Thermoplastics* rejected the notion that patent claims are interpreted differently for patent validity and infringement. Indeed, *Atlantic Thermoplastics* unambiguously stated:

> In any event, claims mean the same for infringement and validity.

Atlantic Thermoplastics, 970 F.2d at 846. The *Atlantic Thermoplastics* court explained that patentability and validity are two separate and distinct concepts: patentability is the administrative standard used by the Patent Office ("PTO") to determine whether to issue a patent, whereas validity is the standard used by courts to revoke issued patent claims.[3] *Id.* "Thus, accommodating the demands of the administrative

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[3] The difference between the administrative patentability standard used by the PTO and the validity standard used by courts is well recognized for all patent claim formats, not just product-by-process claims. *See, e.g., In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).

process and recognizing the capabilities of the trial courts, ***this court treats claims differently for patentability as opposed to validity and infringement***." *Id.* (emphasis added).[4]

Subsequent to the *Abbott* decision, a Federal Circuit panel noted a dichotomy between the interpretation of product-by-process claims for infringement and for validity. *See Amgen Inc. v. F. Hoffmann-LaRoche Ltd.*, 580 F.3d 1340 (Fed. Cir. Sept. 15, 2009).[5] To the extent that the *Amgen* panel decision conflicts with the prior panel opinion in *Atlantic Thermoplastics*, this petition is not the proper vehicle for resolving that tension. Any intra-circuit divergence should be addressed first *en banc* by the Federal Circuit. The present petition for certiorari, of a case that does not address validity in any manner, fails to warrant certiorari.

B. The *En Banc* Decision Below Clarified Intra-Circuit Authority And Does Not Warrant Certiorari

"[I]t is primarily the task of a Court of Appeals to reconcile its internal difficulties." *Wisniewski v.*

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[4] Petitioner also relies on Judge Newman's dissent to the *en banc* decision, which states, without support, that for validity, such claims are "independent of how the products can be made." App. 82. This bare statement cannot create a conflict in the face of the clear statement in *Atlantic Thermoplastics* that "claims mean the same for infringement and validity." *Atlantic Thermoplastics*, 970 F.2d at 846.

[5] None of the eight members of the *Abbott en banc* majority were on the *Amgen* panel.

United States, 353 U.S. 901, 902 (1957). The *en banc* decision below clarified prior panel decisions within the Federal Circuit on the proper interpretation of product-by-process claims for infringement. Review of such *en banc* decisions by the Supreme Court is disfavored. *See* E. Gressman, Supreme Court Practice, 253-54 (citing *Davis v. United States*, 417 U.S. 333, 340 (1974)); J. Moore, Moore's Federal Practice, § 510.21[2], p. 510–15 (3d ed. 2009).

C. The Federal Circuit Followed Appropriate Procedure

Petitioner argues that the Federal Circuit's *sua sponte* decision to take the appeal *en banc* is grounds for grant of certiorari because the Federal Circuit's internal operating procedures provide for notice and opportunity for amicus briefing when proceeding *en banc*. However, as Petitioner is forced to concede, "[the Federal Circuit's] internal operating procedures state that the Federal Circuit is not bound by those procedures." Pet. Br. 9; *see also* United States Court of Appeals for the Federal Circuit, Internal Operating Procedures Rule 1.1[6] ("The court reserves the right to depart from a provision in the IOPs when circumstances require.").

In this instance, the Federal Circuit sought to clarify intra-circuit precedent and plainly saw no utility in seeking additional briefing, or amicus briefs, on this limited issue. Far from acting in a manner which would raise any eyebrows, the Federal Circuit acted commendably to resolve the issue efficiently. In

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[6] Available at http://www.cafc.uscourts.gov/pdf/IOPs122006.pdf.

sharp contrast, Petitioner's claims that they were unfairly denied additional briefing ring hollow where: (1) the petition simply reiterates arguments Judge Newman raised in dissent to the *en banc* panel, (2) no amici filed in support of the petition for certiorari, and (3) Abbott itself, a co-plaintiff below, has abandoned further appeals. In any event, the Federal Circuit's actions in proceeding *en banc* were within the scope of its operating procedures, and cannot form the basis for grant of certiorari.

CONCLUSION

For these reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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November 18, 2009

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No. 09-335

In the
Supreme Court of the United States

ASTELLAS PHARMA, INC.

Petitioner,

v.

LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., and SANDOZ INC.

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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RULE 29.6 STATEMENT

As required by the Court's Rule 29.6, Astellas Pharma, Inc. states that there is no parent corporation and no publicly held company owns 10% or more of its stock.

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60 Brooklyn L. Rev., 1693 (Winter, 1995) 11

REPLY IN SUPPORT OF PETITION FOR *CERTIORARI*

Respondents do not contest that under the Court's binding precedent: "That which infringes, if later, would anticipate, if earlier."[1] *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (U.S. 1889) (internal quotations omitted). Respondents' concession is fatal to their argument that the *en banc* decision below does not contradict the Court's precedent. Two of the respondents argue, however, that the Federal Circuit took the unprecedented step of *sua sponte* issuing an *en banc* opinion over vigorous dissents merely so it could provide unnecessary *dicta*. But those respondents are incorrect, and the Court should grant the petition for *certiorari*.

Petitioner's main argument is that the *en banc* holding violates the Court's precedent because "claims are now interpreted differently for validity purposes than for infringement purposes." Pet. at 11. Lupin argues, however, that the claims are interpreted the same for infringement and validity because if "a company...produced Crystal A *by the*

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[1] The Respondents are: Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva"), and Sandoz Inc. ("Sandoz"). Although Teva and Sandoz are not parties to the Federal Circuit's decision in 2007-1446 (this case), they were appellees in the companion case 2007-1400 (which denied Astellas's request for a preliminary injunction), and they have submitted their briefs under Supreme Court Rule 12.6. Although Astellas is not seeking review of the denial of its motion for a preliminary injunction, Astellas has attached that order to this reply for the Court's convenience.

process described in the '507 patent before that patent's priority date, the invention would have anticipated petitioner's patent claim; and the same product produced by that same process would infringe...if practiced later." Lupin Opp. at 24 (emphasis added). But Lupin's argument does not address Petitioner's argument that, under the Federal Circuit's new rule, the product made by a *different* process anticipates if earlier but does *not* infringe if later. Pet. at 13.

Moreover, any doubt that the *en banc* holding requires different interpretations for infringement and validity has been erased by *Amgen Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009).[2] *Amgen* held that "*[f]or product-by-process claims, that which anticipates if earlier does not necessarily infringe if later.* That is because a product in the prior art made by *a different process can anticipate* a product-by-process claim, but an accused product made by *a different process cannot infringe* a product-by-process claim." *Id.* at 1370 (emphasis added). Thus, the Federal Circuit has now turned product-*by*-process claims into product claims for validity purposes and into product-*and*-process claims for infringement purposes.

Teva argues, however, that the Court should ignore *Amgen* because "[t]o the extent that the *Amgen* panel decision conflicts with...*Atlantic Thermoplastics*...[a]ny intra-circuit divergence should be addressed first *en banc* by the Federal

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[2] *Amgen* issued the day Astellas sent its petition to the printer.

Circuit."[3] Teva Opp. at 10. Teva's argument is both wrong and irrelevant. It is wrong because there is no conflict, as *Atlantic* held that "product-by-process claims are limited by and defined by the *process* [for infringement], determination of patentability [validity] is based on the *product* itself." *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 845 (Fed. Cir. 1992) (emphasis added). Thus, like *Amgen*, *Atlantic* also held that product-by-process claims are interpreted differently for infringement and validity.[4]

Teva's argument is irrelevant because any split was resolved by the *en banc* decision here. *Amgen* was merely following the *en banc* decision as it must. *See Amgen*, 580 F.3d at 1370 (citing to the *en banc* decision). Therefore, the only way to prevent the Federal Circuit's binding *en banc* holding (which requires different claim interpretations for validity and infringement) from improperly overruling *Peters* is for the Court to grant the petition.

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[3] Contrary to Teva's implication, *see* Teva Opp. at 10 n.5, only one member of the unanimous *Amgen* panel dissented from the *en banc* decision.

[4] Teva points to the following dicta in an attempt to gin up a conflict: "In any event, claims mean the same for infringement and validity." *Atlantic*, 970 F.2d at 846. But that quote comes immediately after *Atlantic* demonstrated that it does treat claims differently for "infringement and validity," which is why the quote begins, "In any event." The fact that *Atlantic* tried to make its improper overruling of *Scripps* more palatable by downplaying the significance of its holding cannot change the fact that its holding was a dramatic change in the law.

Lupin argues, however, that "any asymmetry" between how claims are interpreted for infringement versus validity "has been accepted by this Court for more than a century." Lupin Opp. at 26. It bases this argument on its contention that the dissent "did not dispute that the disparity necessarily arises under what it conceded was the 'general rule' described in cases like *BASF*." Lupin Opp. at 26 (*citing* Pet. App at 45, 54). But Lupin provides no support for its incredible claim that this Court "accepts" lower courts ignoring the Court's binding precedent. Moreover, Lupin's characterization of the "general rule" is wrong. "[T]he general rule [is] that new products are claimed without reference to the process by which they are produced." Pet. App. at 45. Product-by-process claims are then an exception to the "general rule" because the process *describes* the product claimed for both validity and infringement purposes. Accordingly, the "asymmetry" that the Court allegedly "accepts" only came about now, where the *en banc* majority has chosen to treat the process as a *description* of the product claimed for validity purposes but as a *limitation* on the product claimed for infringement purposes. The Court should not "accept" this disregard of its precedent and grant the petition for *certiorari*.

Lupin and Sandoz next attempt to change the subject, arguing that the Federal Circuit went *en banc* to issue meaningless *dicta* that has "no effect on the outcome of this litigation." Lupin Opp. at 10; *accord* Sandoz Opp. at 8. Their argument is based on their incorrect claim that it is an established fact

that their products contain only Crystal B and not Crystal A.

Regarding Sandoz, the Federal Circuit correctly noted that "the parties to the *Sandoz* litigation disputed whether Sandoz and Teva's products also contained small amounts of...Crystal A."[5] Pet. App. 34. The Federal Circuit upheld the district court's denial of a preliminary injunction, however, because Astellas, as the moving party, had not proven at the preliminary injunction stage that Sandoz's product contains Crystal A. *Id.* at 36. But that factual issue has not been resolved.

Similarly, regarding the Lupin products, Lupin alleges that its cefdinir is "composed *almost* entirely of Crystal B." Lupin Opp. at 4 (emphasis added). Assuming *arguendo* that statement is true, it still leaves open whether Lupin's products also contain Crystal A. The Federal Circuit held that it need not decide that issue because Astellas had conceded that it had not proven that Lupin practiced the processes described in claims 2-5. Pet. App. at 30. Accordingly, Lupin is wrong when it claims that "[t]he question in this case is whether respondent's use of Crystal B violates the petitioner's patent." Lupin Opp. at 1. Rather, the question in this case is whether Lupin's products contain Crystal A, in addition to Crystal B.[6] Thus, if the Court reverses

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[5] This quote demonstrates that Teva was correct in not joining Sandoz's argument that the *en banc* decision is meaningless dicta.

[6] Lupin incorrectly claims that Astellas abandoned its "theory" that Lupin's products "contained material amounts of Crystal

the Federal Circuit and holds that process steps are not limitations on product-by-process claims, Astellas will then put forth evidence demonstrating that Lupin's products *do* contain Crystal A.

Respondents misunderstand the remainder of Petitioner's arguments. For example, Petitioner explained in its opening brief that the *en banc* decision was wrong because it necessarily led to the panel having to redefine the term "obtainable by" to be "obtained by." Pet. at 28-29. As *Respondents* explained, "it is a fundamental tenet of patent law that the wording of the claims determines the scope of the patent." Sandoz Opp. at 5. But the only way to read the process into the claim as a limitation is to ignore "the wording of the claim" and change "obtainable by" to "obtained by." Thus, Petitioner

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A" because Astellas withdrew its claim for literal infringement of claim 1. Lupin Opp. at 4-5 n.3 (*citing* Pet. App. at 93). But Astellas withdrew that claim because of the difficulty of proving that Lupin's products infringed that claim. As Lupin explained, claim 1 "is a traditional product claim which *further* characterizes the product by reference to its unique x-ray fingerprint from a 'powder X-ray diffraction [PXRD] test.'" Lupin Opp. at 3 (emphasis added). Therefore, to prove infringement under Claim 1, Astellas must show all seven PXRD peaks, which are all limitations under that claim. Pet. App. at 5. But when Crystal A and Crystal B are mixed, as they are in the Lupin product, some of the PXRD peaks created by the Crystal B product obscure some of the seven PXRD peaks required by Claim 1. But claims 2 through 5 do not include the limitation that the product is "*further* characterized" by the seven PXRD peaks. *Id.* at 6. Therefore, Astellas chose only to proceed with those claims because it would be easier to prove that Lupin's products contain Crystal A (along with Crystal B) for those claims.

was not asking the Court to grant *certiorari* to correct the panel's interpretation of the term "obtainable by." Rather, Petitioner was demonstrating that the *en banc* holding is incorrect because it requires courts to change the term "obtainable by" to "obtained by," which puts thousands of patents at risk.[7]

Respondents also misinterpret Petitioner's arguments regarding the Federal Circuit's failure to follow its own procedures. Astellas explained that the Federal Circuit was wrong to issue an *en banc* opinion that was affecting thousands of existing patents without informing either the parties or the public that it was considering changing the law on product-by-process claims. Astellas was not asking the Court to grant *certiorari* because the *en banc* majority lacked jurisdiction to take such a course of action, but rather to ameliorate the harm caused by its failure to follow its own procedures.

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[7] Lupin was correct, however, in stating that Astellas overstated the number of existing patents with the phrase "obtainable by" because, when it ran its search, Astellas erroneously also included patent applications. Lupin Opp. at 16 n.9. Astellas regrets its error. But its error does not change the larger point that thousands of issued patents are at risk. In addition, the fact that there have been nearly 1,000 applications published in the last year with that term (compared to 2,600 issued patents in the previous twenty years) demonstrates that the importance of product-by-process patents is increasing. (Astellas found approximately 958 patent applications based on a search of the Lexis "Utility, Design and Plant Patents" database using the search term "obtainable by" in the segment "claims" for patent applications filed between November 27, 2008, and November 26, 2009.)

Respondents argue, however that the *en banc* majority's failure to follow the Federal Circuit's procedures is harmless because 1) this case is not important, and 2) Judge Newman fully advanced Astellas's arguments. *See* Teva Opp. at 12; Sandoz Opp. at 11-12; Lupin Opp. at 16.

Respondents' contention that this case was not important is based on 1) the fact that no *amicus* briefs were filed, and 2) Abbott did not seek *certiorari*. *Id.* First, *amici* typically do not file at the petitioning stage because even if a petition has merit, the odds against the Court granting *certiorari* are high due to the thousands of petitions that are filed each year. Therefore, in the current economic climate, it is not surprising that *amici* might not choose to expend their limited resources until the merits stage of the proceedings. Second, Abbott (a licensee) is in a very different position than Astellas (the patent holder). Once other generic drug companies were able to market crystalline cefdinir, Abbott's market was destroyed. Thus, Abbott chose not to devote further resources to this lawsuit. Accordingly, Abbott's failure to file a petition for *certiorari* is not evidence that this case is unimportant.[8]

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[8] Teva also argues that this case is not important because it alleges that this issue has only arisen "on two previous occasions in the twenty-five year history of the...Federal Circuit." Teva Opp. at 2. That statement is simply not true because this exact issue was raised in *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1318-19 (Fed. Cir. 2006). Moreover, Teva's argument is also undercut by the fact that the Federal Circuit again addressed this issue in *Amgen Inc.*, 580 F.3d at 1370. Finally, Teva's argument is further undercut by

In any event, all of the Respondent's arguments that this case is unimportant cannot overcome one simple fact: The Federal Circuit decision to hear this case *en banc* which is limited to "question[s] of exceptional importance."[9] Fed. R. App. P. 35(a)(2).

While Astellas agrees that Judge Newman's dissenting opinion ably explains why the majority is wrong, it did not advance Astellas's main argument. What was missing from Judge Newman's dissent was that this Court's precedent *requires* the process to *not* be a limitation in a product-by-process claim because "[t]hat which infringes, if later, [must] anticipate, if earlier." *Peters,* 129 U.S. at 537. While Judge Newman did explain that, under Federal Circuit law, the same interpretation must be used for both infringement and validity, Pet. App. at 81-82, the *en banc* court was free to overrule that

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the numerous district court cases that have addressed this issue. In addition, to the cases cited in Petitioner's opening brief, at least the following published cases all addressed this issue: *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 581-82 & n.21 (D.N.J. 2004); *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 163 F. Supp. 2d 426, 437 (D. Del. 2001); *AK Steel Corp. v. Sollac*, 234 F. Supp. 2d 711, 739 n.1 (S.D. Ohio 2002); *Lucent Techs., Inc. v. Gateway, Inc.*, 509 F. Supp. 2d 912, 927-28 (S.D. Cal. 2007).

[9] A further example of this case's importance is the fact that that the FDA now allows product-by-process claims to be listed in the Orange Book for new drugs. *See* Pet. at 31-32. As Petitioner explained, "the Federal Circuit's decision here contradicts the FDA's decision." *Id.* None of the Respondents contest this argument.

precedent. But the *en banc* court was not free to overrule *Peters*, which was not mentioned in either of the dissents. Thus, because the main thrust of the majority's opinion was that *this Court's precedent requires* that the process be treated as a limitation, when in actuality *this Court's precedent requires* that the process *not* be treated as a limitation, the majority's decision denying Astellas and the public the opportunity to brief this issue was not harmless.

Lupin next argues that cases from the Court support the opinion below. Lupin Opp. at 18-22. As Judge Newman addressed all of those cases, Astellas will not repeat her analysis here. Astellas notes, however, that it explained in its opening brief that virtually every commentator who addressed this issue found that the majority's interpretation of those cases (and by extension, Lupin's interpretation) was wrong. Pet. at 24-25. Not only does Lupin not address that issue, but Lupin fails to point to a single commentator who agrees with Lupin's reading of those cases. Simply put, all the cases cited by Lupin either address old products or are referencing *dicta* that was not relevant to the decision of the case.

Lupin also argues that the Court should deny the petition because Astellas is arguing for a "novel rule," Lupin Opp. at 3, that is much broader than the "the limited 'rule of necessity' advanced by the dissent below." *Id.* at 17. First, Lupin is wrong because Astellas is not asking for a "novel rule." For at least thirty years, product-by-process claims have not been limited to claims that meet the rule-of-necessity. *See In re Steppan*, 394 F.2d 1013, 1019

(C.C.P.A. 1967) (the rule-of-necessity is not supported by the patent statute); *Recent Cases...The Trustees of Columbia University v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (D. Mass. 2000)*, 115 Harv. L. Rev. 923, 924 n.1 (Jan. 2002) (in 1979, the PTO discarded the rule-of-necessity and "now allows inventors to employ product-by-process claims freely").

Second, Lupin is wrong because Astellas is asking for the exact rule put forward by Judge Lourie in his dissent: "When a product is new and the inventor claims it by a process of preparation,...the product-by-process claim should...be interpreted as a product claim that can be infringed even when the product is made by means other than that recited in the claim." Pet. App. 87.

Finally, Lupin argues against product-by-process claims because 1) the product is not "fully disclosed," Lupin Opp. at 27, 2) they claim "an unidentified proxy product," *id.* at 28, and 3) they "unmoor[] patent protection from the disclosures in the patent." *Id.* at 29. But in all three cases, if the product claimed is not fully disclosed, the claim would be invalid for indefiniteness. *See* 35 U.S.C. 112 ¶ 2; Brian S. Tomko, Comment, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-By-Process Patents*, 60 Brooklyn L. Rev., 1693, 1705 (Winter, 1995) (product-by-process claims are proper if "definite"). Lupin also argues that "[u]nder petitioner's view...to determine whether a patent claim is infringed, it would never be enough to simply compare the claims in the

patent with the allegedly infringing product and process." Lupin Opp. at 28. But "[u]nder petitioner's view" (and the rule from *Peters*), proving infringement only involves comparing the product claimed to the alleged infringer's product, without regard to the alleged infringer's process.

CONCLUSION

For the foregoing reasons, along with the reasons stated in Astellas's petition, the petition for *certiorari* should be granted.

Respectfully submitted,

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APPENDIX

Abbott Laboratories, and Astellas Pharma, Inc., Plaintiffs

v.

Sandoz, Inc., Sandoz GmbH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Ranbaxy, Inc., Ranbaxy Laboratories, Ltd., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical, Defendants.

No. 07 C 1721

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

486 F. Supp. 2d 767

May 3, 2007, Decided
May 3, 2007, Filed

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JUDGES: Wayne R. Andersen, District Judge.

OPINION BY: Wayne R. Andersen

MEMORANDUM OPINION AND ORDER

Before the court is plaintiffs Abbott Laboratories ("Abbott") and Astellas Pharma, Inc.'s ("Astellas") motion for a preliminary injunction. Abbott seeks a preliminary injunction preventing defendants Sandoz, Inc. and Sandoz GmbH ("Sandoz") and defendants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. ("Teva") from manufacturing, selling, offering for sale, importing or distributing their respective generic cefdinir products before a decision on the merits in this case.

For the following reasons, the plaintiffs' motion for a preliminary injunction is denied.

BACKGROUND

Cefdinir is an antibiotic which has sales exceeding $ 600 million annually worldwide. In 1983, plaintiff Astellas's corporate predecessor, Fujisawa, developed the compound cefdinir, which treats bacterial infections, and thereafter secured U.S. Patent No. 4,559,334 ("'334 patent"). The '334 patent claimed an amorphous form of cefdinir, which was not useful for making pharmaceutical products because it was difficult to store, unstable, and not appropriately soluble. Astellas then developed a crystalline form of cefdinir, which is practical as a pharmaceutical product, and secured U.S. Patent No. 4,935,507 ("'507 patent") in 1990 on that product. Abbott has the exclusive license for the '507 patent and markets its Omnicef brand cefdinir, a form of crystalline cefdinir sold as two products.

The '334 patent expires on May 6, 2007 at 11:59 p.m., EDT. The '507 patent expires on December 4, 2011. On April 6, 2007, the United States Food and Drug Administration ("FDA") approved defendant Sandoz's Abbreviated New Drug Applications ("ANDA"), Nos. 06-5330 and 06-5337, to market and sell generic cefdinir products. Defendant Teva filed its ANDAs on June 29, 2005 and November 1, 2005 (Nos. 65-332 and 65-368), but the FDA has not yet approved them.

The parties agree that Abbott's '334 patent expiration permits generic products to launch if those new products do not infringe on the '507 patent. The

'507 patent is a crystalline form of cefdinir, namely, cefdinir anhydrate, called "Crystal A" in the '507 patent. Plaintiffs contend that the defendants' generic products, which the parties agree are cefdinir monohydrate, infringe the '507 patent because cefdinir monohydrate is contained within the claims of the '507 patent, and also because the defendants' generic products may contain a small percentage of cefdinir anhydrate (allegedly approximately 2% for Teva, and approximately .2% for Sandoz). Defendants claim that their competing products do not infringe because cefdinir monohydrate is not covered by the claims in the '507 patent and deny that their products contain any cefdinir anhydrate at all.

DISCUSSION

In order to prevail on a motion for preliminary injunction, plaintiffs must show (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001); *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir.1994). Plaintiff has the burden of proving each of these factors. *Roland v. Air Line Employees Ass'n, Int'l*, 753 F.2d 1385, 1392 (7th Cir. 1985).

Because the present case arises under United States patent law, the Patent Act grants authority to this court to grant or deny an injunction to prevent the infringement of a patent.

> The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

35 U.S.C. § 283. We begin our discussion by examining each of the required elements for a preliminary injunction.

The first element of a motion for preliminary injunction is to determine whether the moving party likely will succeed on the merits of the underlying litigation. In patent cases, the movant has an added burden. Here, plaintiffs must show that (1) they will likely prove that defendants infringed the '507 patent, and (2) their infringement claim will likely withstand defendants' challenges to the validity and enforceability of the '507 patent. See *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006). "In other words, if [defendants] raise a 'substantial question' concerning validity, enforceability, or infringement (i.e. assert a defense that [plaintiff] cannot show 'lacks substantial merit') the preliminary injunction should not issue." *Id.*, quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

In order to assess the likelihood of infringement, the court must (1) first determine, as a matter of law, the correct meaning and scope of the asserted claims, and then (2) compare the properly construed claims to the accused infringing product. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967,

970-71 (Fed. Cir. 1995); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998).

Scope of Claims

In a carefully considered and well written Markman ruling, United States District Judge Robert E. Payne, of the United States District Court for the Eastern District of Virginia, Richmond Division, held the following regarding construction of the '507 patent.

> Claims 2-5 of the '507 patent are construed as product-by-process claims. The '507 patent's disputed claim terms have the following definitions:
>
> > (1) "Crystalline" means "Crystal A;"
> >
> > (2) "shows" requires the display of a powder X-ray diffraction pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display;
> >
> > (3) "peaks" is the plural of "peak;" a "peak" exists at a powder x-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to

> "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement; "noise" refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test;
>
> (4) "about" encompasses measurement errors inherently associated with powder X-ray diffraction testing.

Lupin, Ltd. v. Abbott Labs., 484 F. Supp. 2d 448 (E.D. Va. 2007). The parties have stipulated that Judge Payne's ruling shall be adopted by this court as its determination, as a matter of law with respect to this preliminary injunction proceeding, of the correct meaning and scope of the asserted claims. Therefore, this court hereby adopts Judge Payne's Markman ruling.

First we must resolve the parties' disagreement as to the correct interpretation of Judge Payne's ruling. Afterwards, we will analyze their arguments and evidence to determine whether the defendants' products in fact infringe the '507 patent. We will begin this analysis with a closer look at the actual '507 patent itself.

The '507 Patent

The first claim of the '507 patent construed by Judge Payne is the following:

> 1. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydrox-yiminoacetamido]-3-vinyl-3-cephem.-4-carboxylic acid (syn isomer) which shows the peaks at the diffraction angles shown in the following table in its powder X-ray diffraction pattern:
>
> | diffraction angle ([degree]) |
> |---|
> | about 14.7 |
> | about 17.8 |
> | about 21.5 |
> | about 22.0 |
> | about 23.4 |
> | about 24.5 |
> | about 28.1 |

U.S. Patent No. 4,935,507 col. 16 11.12-28 (filed Aug. 8, 1998). Based on this first claim, Judge Payne ruled, and the parties agree, that the crystalline cefdinir described in Claim 1, and in fact in Claims 2-5 (not reproduced here) is "Crystal A." They do, however, disagree as to which forms of crystalline cefdinir fall within the definition of "Crystal A." The plaintiffs, predictably enough, maintain that the defendants' products, although different substances than the plaintiffs' cefdinir anhydrate product, are

included within the definition of Crystal A. Defendants, of course, disagree.

They also disagree as to how to interpret Judge Payne's ruling on "peaks" and "about." Finally, they disagree on how to construe "powder X-ray diffraction pattern" ("PXRD"), which was not discussed in Judge Payne's ruling. All three of these disagreements are critical to our final determination; therefore, we will examine them each in turn.

Crystal A

There is no more important aspect of this lawsuit than defining the scope of the '507 patent, which centers upon determining the definition of Crystal A as Judge Payne construed it. Our guiding principle in this determination comes from Judge Payne's decision, when he quoted the Federal Circuit. "[A]lthough the claims are not necessarily limited to the preferred embodiment of the invention, 'neither do the claims enlarge what is patented beyond what the inventor has described as the invention.'" *Lupin*, 484 F. Supp. 2d 448, quoting *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001). Judge Payne wrote that Claims 1-5 "define 'Crystal A' and, accordingly, one is justified in reading 'crystalline cefdinir' to mean 'Crystal A' throughout the claims." *Lupin*, 484 F. Supp. 2d 448. Plaintiffs seize on Judge Payne's follow up statement, that "the Court is not affirmatively defining Crystal A to be anything other than what the claims say it is." 484 F. Supp. 2d 448. The crux of their argument, however, arises out of Judge Payne's next statement:

> The claims explicitly define what Crystal A is, but only implicitly define what it is not. At this juncture, it is neither necessary nor appropriate to decide whether any known forms of cefdinir are necessarily excluded from the scope of the '507 patent's claims as a consequence of defining the '507 patent's invention to be Crystal A. The Court notes that . . . the '507 patent's specification quite clearly distinguishes the '507 patent's invention (Crystal A) from the forms of cefdinir disclosed in the '334 patent.

484 F. Supp. 2d 448. The plaintiffs focus on Judge Payne's statement, that "any subsequently discovered crystalline form of cefdinir that features the seven peaks in Claim 1 is, by definition, Crystal A, and not something else." 484 F. Supp. 2d 448. They conclude that, in order to prove infringement, they "are only required to demonstrate the presence of the seven peaks of claim 1, which define Crystal A, and not to show the peaks of claim 1 as that phrase is used in the claim." Pl. Reply Br. at 3. Defendants claim that the '507 patent contains no discussion or disclosure of a crystalline form of cefdinir other than "Crystal A, "and that their products are not Crystal A.

For the reasons explained below, we agree with defendants' interpretation of Judge Payne's construction of the '507 patent that the '507 patent is limited only to Crystal A as disclosed in the patent,

which does not include defendants' products within the claims set forth in the patent.

Show the peaks

Powder x-ray analysis of a crystalline substance enables scientists, and perhaps even judges, to identify the substances used in compounds. Judge Payne ruled that "a 'peak' exists at a powder x-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to 'noise' if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement. . ." 484 F. Supp. 2d 448. Plaintiffs maintain that this is a strict definition, based on Judge Payne's statement that "any intensity requirement, whether absolute or relative, might unjustifiably limit the scope of the '507 patent to cover only the pure form of Crystal A." 484 F. Supp. 2d 448. Nothing in the patent, writes Judge Payne, indicates that Crystal A is claimed only in its pure form. 484 F. Supp. 2d 448. The plaintiffs maintain, as will be shown in the infringement analysis below, that, because Judge Payne appeared to reject the intensity requirement proposed by the plaintiff in *Lupin,* any peak which can be shown at the correct diffraction angle will suffice to satisfy the peak requirement in Claim 1. We believe, however, that this interpretation of Judge Payne's opinion is flawed and is rejected by Judge Payne's reasoning.

While it is true that, in the *Lupin* case, Judge Payne rejected plaintiff Lupin's argument that peaks referred only to the most intense features in the PXRD pattern and instead held that peaks referred

simply to powder x-ray diffraction angles that corresponded to an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement, plaintiff's resulting interpretation of the definition misunderstands Judge Payne's reasoning.

Judge Payne notes that "the only 'peaks' listed in the '507 patent correspond with distinctive features of significant intensity, which, as indicated by Figure 1 [of the '507 patent], have obvious rises and falls before and after reaching a single apex." *Lupin*, 484 F. Supp. 2d 448. Although Claim 1 does not explicitly address intensity of peaks and Judge Payne did not explicitly "import" an intensity requirement into the claim, Judge Payne notes that the PXRD angles listed in Claim 1 correspond with the "most intense and pointed features in Figure 1 of the patent's specification" and "the charts displayed in columns 12 and 14 of the specification, which mathematically describe 'peaks,' list no peak smaller than eight percent of the tallest listed peak's intensity." *Id.*

Judge Payne's definition of peaks does contain a limiting feature, specifically "an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement." Judge Payne did, however, explicitly reject peaks which were "nothing like the features displayed in Figure 1." Judge Payne continues to say that "[s]uch an interpretation of 'peaks' is nonsensical. Not only is it totally unrelated to the 'peaks' identified in the

specification, but it would fail to describe 'distinguishing' features at all." 484 F. Supp. 2d 448. He also notes that "the '507 patent simply does not support a reading of 'peaks' under which a 'peak' would exist at every point of measured intensity above the background noise, and nothing in the record indicates that person of ordinary skill in the art would accept such a definition of 'peaks.'" *Id.*

About

Judge Payne held that "'about' encompasses measurement errors inherently associated with powder X-ray diffraction testing." The parties disagree as to the measurement errors which comport with this holding. Plaintiffs maintain that the standard deviation is +/- .20 [degree]. Defendants maintain that the standard deviation is +/- .10 [degree]. Both sides presented experts who testified as to publications supporting one or the other methods, but ultimately we were persuaded by the defendants' expert, Dr. Alan Pinkerton, who asserted that the allowable variability in PXRD pattern peak position is +/- .10 [degree] a position supported by the U.S. PHARMACOPEIA XXI (1985).

The plaintiff's expert, Dr. Jerry Atwood, also referred to the U.S. PHARMACOPEIA, but interpreted the phrase "20 values should typically be reproducible to +/- .10 [degree] or 0.20 degrees," see *id.,* as indicating the correct standard measurement error is +/- .20 [degree]. We interpret the ".20 degrees" in this text as limiting the total variance plus and minus to .20 [degree] Dr. Atwood's conclusion could result in a measurement differentiation of as much as .40 [degree], a result we feel is inconsistent with the

U.S. PHARMACOPEIA. We therefore interpret Judge Payne's holding of a measurement error inherently associated with powder X-ray diffraction testing to be +/- .10 [degree].

Powder X-ray Diffraction Pattern

Claim I states that Crystal A shows the peaks at the diffraction angles in its powder X-ray diffraction pattern. Judge Payne did not construe the meaning of the term "powder X-ray diffraction" in his opinion. Plaintiffs contend that they will be able to demonstrate infringement by testing a single crystal using a [theta]/[theta] X-ray diffractometer and a synchroton which then calculates the PXRD pattern. Defendants claim that Claim 1 requires that the pattern must show the peaks using conventional powder x-ray diffraction. They also claim that because the '507 patent does not mention the synchroton, it cannot be used to demonstrate infringement. We disagree. A plain reading of Claim 1 does not use the word "conventional." The term "powder X-ray diffraction" is used a modifier for the word "pattern," one of the few terms not at issue in this case. Because we do not find that the '507 patent specifies one particular manner of producing a powder X-ray diffraction pattern, we reject defendants' argument that a single crystal diffraction which calculates a powder X-ray diffraction is disallowed.

Summary of Scope Analysis

We close our scope analysis of the '507 patent with the following conclusions, reaffirming once again our adoption of Judge Payne's April 27, 2007 Markman ruling. We find that (1) the '507 patent is

limited only to Crystal A as embodied in the patent; (2) while a "peak" exists at a powder x-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement, a peak does not exist at every point of measured intensity above the background noise; (3) the measurement error inherently associated with powder X-ray diffraction testing is +/- .10 [degree]; and (4) the '507 patent does not specify one particular manner of producing a powder X-ray diffraction pattern.

Infringement

We must now determine whether the plaintiffs are likely to be able to prove that the defendants have in fact infringed the '507 patent by comparing the properly construed claims to the accused infringing products. For a product literally to infringe a patent claim, every limitation recited in a properly construed claim must be exactly present in the accused product. *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1998). Infringement may also be established under the doctrine of equivalents. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997). In order to establish infringement under the doctrine of equivalents, there must be a showing that the difference between the patent and the accused product perform "the substantially same function in substantially the same way with substantially the same result as each claim limitation of the

patent." *AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1326 (Fed. Cir. 2007).

Accordingly, we will examine whether cefdinir monohydrate infringes the '507 patent. We will also examine whether the defendants' cefdinir monohydrate contains within it any cefdinir anhydrate. Finally, we will examine whether the defendants' cefdinir monohydrate is equivalent to cefdinir anhydrate under the doctrine of equivalents. In order to make these determinations, we begin by turning once again to the requirements of Claim 1.

Claim 1 requires that, in order to characterize a crystalline structure as Crystal A or an accused product as infringing Crystal A, plaintiffs must show the peaks at seven diffraction angles in its powder X-ray diffraction pattern: about 14.7, about 17.8, about 21.5, about 22.0, about 23.4, about 24.5, about 28.1. We have already held that "about" means +/- .10 [degree], so our analysis for each diffraction angle will be limited to +/- .10 [degree].

We begin our analysis by considering plaintiffs' claim of literal infringement.

Literal Infringement

Plaintiffs advance two arguments to support their claim of literal infringement. First, they claim that the defendants' respective cefdinir products infringe the '507 patent because they contain cefdinir monohydrate, which shows the seven peaks in claim 1 and is obtainable by any of the processes of claims 2 through 4. Second, they claim that the defendants' respective cefdinir products infringe the '507 patent because they contain cefdinir anhydrate, which

shows the seven peaks in claim 1 and is obtainable by any of the processes of claims 2 through 5. As we have already established above, defendants' acknowledge that their products are in fact comprised in large or total part of cefdinir monohydrate, which they claim is not covered by the '507 patent, but which they claim is covered instead by the '334 patent, which expires on May 6, 2007. Additionally, defendants' claim that their products do not contain cefdinir anhydrate and that any of the shown peaks in common with their products and cefdinir anhydrate are due to the characteristics of cefdinir monohydrate.

The obvious place to start is to ask whether cefdinir monohydrate does in fact meet each of the peaks required in Claim 1. Plaintiffs claim that cefdinir monohydrate infringes because it shows the peaks in Claim 1, and thereby accords with Judge Payne's statement that "any form of crystalline cefdinir which displays peaks at the seven diffraction angles listed in Claim 1 is 'distinguished' as Crystal A." In response to the court's questions, plaintiffs' expert, Dr. Atwood, agreed that there were crystalline substances which were not covered by the '507 patent. Hearing Tr. 129. The defendants point directly to another crystalline substance, "Crystal B," which they claim (1) is their product, cefdinir monohydrate, (2) is described in the Japanese '199 patent, and (3) is covered by the '334 patent, specifically example 16.

To allege the infringement, the plaintiffs rely on an interpretation of Judge Payne's analysis that we have rejected in this opinion, that a peak exists at every point of measured intensity above the back-

ground noise. Plaintiffs used SCXRD analysis to calculate a powder X-ray diffraction pattern and found peaks which they claimed matched all seven peaks listed in Claim 1. They demonstrated through the use of visual charts the peaks which they claim matched the diffraction angles listed in Claim 1.

Dr. Atwood claims that for each peak listed in Claim 1, there was a corresponding peak in the PXRD pattern for cefdinir monohydrate, and listed them as follows: 14.84, 17.83, 21.33, 21.98, 23.53, 24.58, and 28.09. Only four of these seven peaks are within the +/- .10 [degree] that we have allowed as the definition for "about" in Claim 1. On that basis alone, the plaintiffs' claim of literal infringement fails, because in order for there to be literal infringement, each and every limitation of the claim must be met. But there are three more reasons.

First, while the diffraction angles listed above imply a story of closely related peaks, the visuals shown in the plaintiffs' exhibits and at the hearing tell an entirely different story, which is that cefdinir monohydrate is a *different substance* than cefdinir anhydrate. When the PXRD patterns for both substances are placed next to one another, they simply do not match. The seven peaks described in the '507 patent are tall and dramatically distinguished from the remainder of the PXRD pattern. Similarly, the PXRD for cefdinir monohydrate shows tall and dramatically distinguishing peaks. None of these prominent peaks for the cefdinir anhydrate match the ones for the cefdinir monohydrate. Dr. Atwood admitted as much when he said "by comparing the entire pattern for each form, it is clear that cefdinir 'Crystal A' and crystalline cefdinir monohydrate are

different crystal forms." While plaintiffs are understandably eager to interpret the '507 patent to include cefdinir monohydrate, we believe they are simply so different that they undermine the claims of literal infringement.

Second, in order to demonstrate infringement, the plaintiffs used a mathematical procedure called pseudo-Voigt fitting, which is used to determine accurately the size and position of smaller peaks which are partially overlapped by larger neighboring peaks. The resulting peaks "exist" but are "nothing like the features displayed in Figure 1. Indeed, [they] eviscerate" any of the descriptive value of the word peaks in the '507 patent. Indeed, the "peaks" were peaks only when interpreting Judge Payne's opinion in the awkward manner with which we disagree.

Third, the evidence does not convince us that there in fact are trace amounts of cefdinir anhydrate contained within the cefdinir monohydrate in defendants' products. Moreover, there is no evidence that, even if there were traces, that those trace amounts could be a contributing factor in the efficacy of the defendants' products. If there is a small amount of cefdinir anhydrate in defendants' products, we do not conclude that this could cause literal infringement of the '507 patent.

Finally, we heard persuasive evidence identifying the defendants cefdinir monohydrate as Crystal B. PXRD patterns of the defendants cefdinir monohydrate were superimposed on PXRD patterns of Crystal B; they matched in peaks and intensity. Further, defendants argued, and plaintiffs did not rebut, that

the reason that plaintiffs left reference to Crystal B out of the '507 patent was because Crystal B was contained within Example 16 of the '334 patent. Had Crystal B been included in the '507 patent application, the patent would not have issued because Crystal B had already been disclosed. We know that Crystal B was known to the plaintiffs because it had been included in the Japanese '199 patent. Thus we conclude that the plaintiffs deliberately excluded from the definition of Crystal A, cefdinir monohydrate, which is Crystal B.

Doctrine of Equivalents

Plaintiffs claim that the defendants' respective cefdinir products infringe the '507 patent under the doctrine of equivalents. They assert that Dr. Atwood's testimony about the similarity of shelf life, dissolution rate and bioavailability between cefdinir monohydrate and cefdinir anhydrate show conclusively that defendants' products infringe claims 1-5 of the '507 patent under the doctrine of equivalents. Under cross-examination, however, Dr. Atwood failed to establish that he had supported his opinion with empirical or substantive evidence. While an expert may offer an opinion on infringement, we need not credit unsupported conclusions. *See Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir.1997) ("Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness").

Plaintiffs make the second argument that defendants' assertion to the FDA that their products were bioequivalent to cefdinir anhydrate in their ANDAs is an admission that they were infringing the '507

patent under the doctrine of equivalents. We disagree with this position. See *Upjohn Co. v. Mova Pharm. Corp.*, 31 F.Supp.2d 211, 215 n.2 (D.P.R. 1998) ("[An] admission of bioequivalence is not an admission of infringement under the doctrine of equivalents. They are two distinct concepts.") If bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of a patent.

CONCLUSION

The plaintiffs have failed to persuade the court they are likely to be able to prove that defendants have literally infringed on the '507 patent and failed to show that defendants have infringed using the doctrine of equivalents. Moreover, they have failed to establish that defendants' products contain amounts of cefdinir anhydrate, if any, to cause infringement on the '507 patent. Because we have found that the plaintiffs have not shown that they are reasonably likely to succeed on the merits, there is no need for us to analyze the remainder of the factors required for the granting of a preliminary injunction. See *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 973-974 (Fed. Cir. 1996); *Payless Shoesource Inc. v. Reebok Int'l Ltd.*, 998 F.2d 985, 988 (Fed. Cir. 1993). The defendants have successfully raised a substantial question concerning infringement, and therefore, the preliminary injunction should not issue.

For all the foregoing reasons, the plaintiffs' motion for a preliminary injunction [65] is denied.

It is so ordered.

Wayne R. Andersen

District Judge

Dated: May 3, 2007